IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MOMENTA PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS, INC., MYLAN INC., VIATRIS INC., MYLAN TEORANTA, NATCO PHARMA LTD., AND GLAND PHARMA, LTD., Defendants.	Civil Action No. 2:22-CV-750 **JURY TRIAL DEMANDED**

DEFENDANTS MYLAN PHARMACEUTICALS INC.'S, MYLAN INC.'S, AND VIATRIS INC.'S ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT WITH DEFENSES AND COUNTERCLAIMS

Defendant Mylan Pharmaceuticals Inc. ("MPI"), Mylan Inc., and Viatris Inc. ("Viatris") (MPI, Mylan Inc., and Viatris collectively referred to as the "Domestic Defendants") by its undersigned attorneys, answers and responds to each of the allegations of Plaintiff Momenta Pharmaceuticals, Inc. ("Momenta") below.

Momenta's inclusion of footnotes throughout the Complaint does not comply with Federal Rule of Civil Procedure 10(b), requiring that allegations be stated "in numbered paragraphs, each limited as far as practicable to a single set of circumstances." As such, no response is required to these footnotes.

NATURE OF THE ACTION[1]

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This action arises out of Defendants' manufacture, importation, and sale of generic glatiramer acetate products (herein after referred to as "Glatiramer Acetate Injection 20 mg/mL" and "Glatiramer Acetate Injection 40 mg/mL" or, collectively, "Mylan Glatiramer Acetate Products") made by Momenta's patented methods, prior to the expiration of United States Patent No. 8,859,489 ("the '489 patent",

[1] The headings included in the Complaint are included herein for convenience only.

attached hereto as Exhibit 1) and United States Patent No. 9,395,374 ("the '374 patent", attached hereto as Exhibit 2).

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, admitted that Momenta purports to bring an action for patent infringement under the patent laws of the United States for infringement of United States Patent No. 8,859,489 ("the '489 patent") and United States Patent No. 9,395,374 ("the '374 patent") (the '489 patent and the '374 patent collectively, the "patents-in-suit"), and that the action purports to relate to MPI's Glatiramer Acetate Injection 20 mg/mL ("MPI's 20 mg GA Products") and Glatiramer Acetate Injection 40 mg/mL ("MPI's 40 mg GA Products") (MPI's 20 mg GA Products and MPI's 20 mg GA Products collectively "MPI's GA Products"). The Domestic Defendants deny the remaining allegations of Paragraph 1.

THE PARTIES

2. Plaintiff Momenta is a Delaware corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ 08560.

ANSWER: The Domestic Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 2 and therefore deny those allegations.

3. Momenta is a wholly owned subsidiary of Johnson & Johnson.

ANSWER: The Domestic Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 3 and therefore deny those allegations.

4. Upon information and belief, Defendant MPI is a corporation organized and existing under the laws of West Virginia, with a principal place of business at 781 Chestnut Ridge, Morgantown, West Virginia 26505. MPI is registered with the Pennsylvania Department of State, as a business operating in Pennsylvania as Entity No. 232038. (Ex. 3 – Pennsylvania Department of State Business Entity Report for MPI). Upon information and belief, MPI has appointed CT Corporation System of Dauphin County, Pennsylvania, as its registered agent for service of process in Pennsylvania. (*Id.*) MPI is registered with the Pennsylvania Department of Health Drug, Device and Cosmetic Program as a "Distributor of Prescription

Drugs, Controlled Substances and/or Seller/Distributor of Medical Gases" under Certificate No. 3000008447. (Ex. 4 – Pennsylvania Department of Health Public Lookup (https://apps.health.pa.gov/ddc/DDCPublicLookup.asp); Ex. 5 – Pa. Dep. of State Certificate Type Description).

ANSWER: Admitted that MPI is a corporation organized and existing under the laws of West Virginia. Mylan denies that MPI has a place of business at 781 Chestnut Ridge, Morgantown, West Virginia 26505. Admitted that MPI is registered with the Pennsylvania Department of Health under Certificate No. 3000008447. Admitted that MPI has appointed CT Corporation System as an agent for service of process. Momenta makes no specific allegations as to the exhibits cited in Paragraph 4 and therefore no response is required as to those exhibits. The Domestic Defendants deny any remaining allegations in Paragraph 4.

5. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1000 Mylan Boulevard, Canonsburg, PA, 15317. (Ex. 6 – Mylan Inc. Form S-4 2018).

ANSWER: Admitted that Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1000 Mylan Boulevard, Canonsburg, PA, 15317. Momenta makes no specific allegations as to the exhibits cited in Paragraph 5 and therefore no response is required as to those exhibits. The Domestic Defendants deny any remaining allegations in Paragraph 5.

6. Upon information and belief, Mylan Teoranta is a corporation organized and existing under the laws of Ireland, with a principal place of business at Kilrow East, Inverin, Co. Galway, Ireland. (Ex. 7 – Viatris Ireland Contact Page (https://www.viatris.com/en-ie/lm/ireland/contact-us); Ex. 8 – Bladder Smart Page (https://www.bladdersmart.org/en/terms-and-conditions)). Upon information and belief, Mylan Teoranta trades under the name Mylan Institutional. (*See, e.g.*, Ex. 9 – Mylan Name Change Letter (http://www.oncoscan.ro/documente/autorizatii/Mylanlegalnamechange-Cystistat.pdf); Ex. 10 – Irish Times Article (https://www.irishtimes.com/business/health-pharma/court-refusesinjunctions-in-pharma-patent-case-1.3521362); Ex. 8 – Bladder Smart Page (https://www.bladdersmart.org/en/terms-and-conditions)).

ANSWER: Admitted that Mylan Teoranta is a corporation organized and existing under the laws of Ireland, with a principal place of business at Kilrow East, Inverin, Co. Galway, Ireland, and that it does business under the Irish-registered d/b/a name Mylan Institutional. Momenta makes no specific allegations as to the exhibits cited in Paragraph 6 and therefore no response is required as to those exhibits. The Domestic Defendants deny any remaining allegations set forth in Paragraph 6.

7. Upon information and belief, Defendant Viatris is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317. (Ex. 11 – Viatris Inc. Form 10-K, 2021, at 1). Viatris is registered with the Pennsylvania Department of State, as a business operating in Pennsylvania as Entity No. 7166717. (Ex. 12 – Pennsylvania Department of State Business Entity Report for Viatris).

ANSWER: Admitted that Viatris is a corporation organized and existing under the laws of Delaware, with a principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317. Admitted that Viatris is registered with the Pennsylvania Department of State as entity number 7166717. Momenta makes no specific allegations as to the exhibits cited in Paragraph 7 and therefore no response is required as to those exhibits. The Domestic Defendants deny the remaining allegations set forth in Paragraph 7.

8. Upon information and belief, MPI is a wholly owned subsidiary of Mylan Inc., which is a wholly owned subsidiary of Viatris. (Ex. 11 – Viatris Inc. Form 10-K, 2022, at 165, 167; *see Merck Sharp & Dohme B.V. et al. v. Mylan Pharms. Inc. et al.*, No. 1:20-cv-00061-JPB (N.D. W. Va.), ECF No. 20, ¶ 7).

ANSWER: Admitted that MPI is an independently operated, indirectly wholly owned subsidiary of Mylan Inc., which is an independently operated, indirectly wholly owned subsidiary of Viatris. Momenta makes no specific allegations as to the exhibit cited in Paragraph 8 and therefore no response is required as to that exhibit. The Domestic Defendants deny any remaining allegations in Paragraph 8.

9. Upon information and belief, Defendant Mylan Teoranta is a wholly owned subsidiary of Viatris, and is an affiliate of MPI. (Ex. 11 – Viatris Inc. Form 10-K, 2022, at 163).

ANSWER: Admitted that Mylan Teoranta is an independently operated, indirectly wholly owned subsidiary of Viatris, and is an affiliate of MPI. Momenta makes no specific allegations as to the exhibit cited in Paragraph 9 and therefore no response is required as to that exhibit. The Domestic Defendants deny any remaining allegations in Paragraph 9.

10. Upon information and belief, Defendant Natco is a corporation organized and existing under the laws of India, with a registered office and corporate headquarters at Natco House, Road No. 2, Banjara Hills, Hyderabad 500 034, India. Natco is a pharmaceutical manufacturer with active pharmaceutical ingredient facilities, finished dosage facilities, and a research center, all located in India. (Ex. 13 – Rao Declaration).

ANSWER: Paragraph 10 relates only to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. Momenta makes no specific allegations as to the exhibit cited in Paragraph 10 and therefore no response is required as to that exhibit. The Domestic Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 10, and therefore deny those allegations.

11. Upon information and belief, Defendant Gland Pharma Limited ("Gland") is an Indian corporation with a registered office at 6-3-865/1/2 Greenland Apartments, Ameerpet, Hyderabad, 500 016, India. Gland is a pharmaceutical manufacturer whose activities include active pharmaceutical ingredient manufacture, formulation development, and finished dosage manufacturing. (Ex. 14 – Gland Brochure).

ANSWER: Paragraph 11 relates only to Gland. Gland has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. Momenta makes no specific allegations as to the exhibit cited in Paragraph 11 and therefore no response is required as to that exhibit. The Domestic Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 11 and therefore deny those allegations.

12. Upon information and belief, Defendants, themselves and through their subsidiaries, affiliates, and agents, develop, manufacture, import, market, distribute, and/or sell generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this District.

ANSWER: Admitted that MPI imports and markets certain pharmaceutical products in the United States. The Domestic Defendants deny the remaining allegations of Paragraph 12.

13. Upon information and belief, as discussed in more detail below, Defendants are agents of each other and/or work in concert with respect to the development, manufacture, regulatory approval, marketing, import, sale, and/or distribution of pharmaceutical products, including the Mylan Glatiramer Acetate Products, throughout the United States, including in this District.

ANSWER: Denied.

14. Upon information and belief, Defendants developed, manufacture, market, sell, import, and/or distribute the Mylan Glatiramer Acetate Products, including in this District.

ANSWER: Admitted that MPI imports into and markets MPI's GA Products in the United States. The Domestic Defendants deny the remaining allegations of Paragraph 14.

THE PATENTS-IN-SUIT

15. The '489 patent, entitled "Water-Mediated Control of Depolymerization Step of Glatiramer Acetate Synthesis," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on October 14, 2014, naming as inventors Claire Coleman, John Schaeck, and Alicia Thompson. A copy of the '489 patent is attached hereto as Exhibit 1.

ANSWER: Admitted that the '489 patent, entitled "Water-Mediated Control of Depolymerization Step of Glatiramer Acetate Synthesis," lists on its face an issuance date of October 14, 2014, and names as inventors Claire Coleman, John Schaeck, and Alicia Thompson. Also admitted that Exhibit 1 purports to be a copy of the '489 patent. The Domestic Defendants lack sufficient knowledge or information as to any remaining allegations of Paragraph 15 and therefore deny those.

16. The ’374 patent, entitled “Analysis of Amino Acid Copolymer Compositions,” was duly and legally issued by the United States Patent and Trademark Office on July 19, 2016, naming as inventors Xiangping Zhu, Zachary Shriver, Yanjie Jiang, Corinne Bauer, James Eric Anderson, and Peter James Ahern. A copy of the ’374 patent is attached hereto as Exhibit 2.

ANSWER: Admitted that the ’374 patent, entitled “Analysis of Amino Acid Copolymer Compositions,” lists on its face an issuance date of July 19, 2016, and names as inventors Xiangping Zhu, Zachary Shriver, Yanjie Jiang, Corinne Bauer, James Eric Anderson, and Peter James Ahern. Also admitted that Exhibit 2 purports to be a copy of the ’374 patent. The Domestic Defendants lack sufficient knowledge or information as to any remaining allegations of Paragraph 16 and therefore deny those.

17. Momenta is the exclusive and lawful owner of all rights, title, and interest in both of the patents-in-suit, and has the right to bring this suit and to recover damages for any current or past infringement of both of the patents-in-suit.

ANSWER: The Domestic Defendants are without sufficient knowledge or information as to the allegations of Paragraph 17 and therefore deny those.

18. The patents-in-suit are directed to commercial manufacturing methods invented by Momenta in their development of Glatopa® (glatiramer acetate injection), a glatiramer acetate product used in the treatment of multiple sclerosis and approved by the United States Food & Drug Administration (“FDA”).

ANSWER: The Domestic Defendants are without sufficient knowledge or information as to the allegations of Paragraph 18 and therefore deny those.

19. The ’374 patent discloses and claims novel methods for manufacturing pharmaceutical compositions comprising glatiramer acetate. The methods include steps for controlling pyro-glutamate content by measuring it and processing a copolymer to produce a pharmaceutical composition comprising glatiramer acetate only if the measured pyro-glutamate content of the copolymer is within a specific range (2000–7000 parts per million (ppm)). The inventors of the ’374 patent discovered that controlling the pyro-glutamate content during the manufacture of glatiramer acetate controls the quality of the glatiramer acetate produced, and the ’374 patent describes and claims novel manufacturing methods

that utilize analytical process steps that enable controlling the pyro-glutamate levels as part of the manufacturing process.

ANSWER: The Domestic Defendants are without sufficient knowledge or information as to the allegations of Paragraph 19 and therefore deny those.

20. The '489 patent discloses and claims novel methods for preparing compositions comprising purified glatiramer acetate in which the depolymerization step of the glatiramer acetate preparation process is controlled by ensuring the presence of water during that step in an amount such that the pyro-glutamic acid ("pyro-Glu") levels of the resulting glatiramer acetate are in a specific range (2000–7000 parts per million (ppm)). [footnote 3 omitted]

ANSWER: The Domestic Defendants are without sufficient knowledge or information as to the allegations of Paragraph 20 and therefore deny those.

BACKGROUND

21. Multiple sclerosis is a chronic inflammatory disease of the central nervous system that affects more than 2 million individuals globally and approximately 400,000 individuals in the United States. (*See* Ex. 57 – Bell 2018, at 2). Physicians have combatted the disease for decades, but a silver bullet has eluded discovery: while there are numerous treatment options to manage symptoms or slow disease progression, there is no cure. *Id*.

ANSWER: Momenta makes no specific allegations as to the exhibit cited in Paragraph 21 and therefore no response is required as to that exhibit. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 21 and therefore deny those.

22. One of these treatment options is glatiramer acetate. Also known as copolymer-1, glatiramer acetate is a heterogeneous mixture of peptides comprising four amino acids and is similar in structure to the myelin basic protein, which is thought to play an important role in the pathogenesis of multiple sclerosis. *Id*. at 2. Teva was the first to seek approval in the United States to market glatiramer acetate as a treatment for multiple sclerosis.

ANSWER: Admitted that glatiramer acetate is a treatment option for multiple sclerosis ("MS"). Admitted that glatiramer acetate is also known as copolymer-1. Admitted that glatiramer acetate is a mixture of peptides comprising four amino acids. Momenta makes no specific allegations as to the exhibit cited in Paragraph 22 and therefore no response is required as to that exhibit. The

Domestic Defendants lack sufficient knowledge or information as to the remaining allegations of Paragraph 22 and therefore deny those.

Teva's Copaxone® (glatiramer acetate injection) Products

23. Teva's New Drug Application ("NDA") for glatiramer acetate was approved by the FDA in 1996, and Teva began selling the drug under the trade name Copaxone® (glatiramer acetate injection) in the United States in 1997. For almost twenty years, Copaxone® (glatiramer acetate injection) was the only glatiramer acetate product available on the market. Copaxone® (glatiramer acetate injection), sold in a once-daily 20 mg/mL formulation and a three-times weekly 40 mg/mL formulation, is one of the leading products marketed to treat relapsing forms of multiple sclerosis, and is frequently prescribed as a first-line therapy in newly diagnosed patients. [footnote 4 omitted]

ANSWER: Admitted that Teva's Copaxone® (glatiramer acetate injection) was approved by the FDA in 1996 and that Teva began selling Copaxone® in 1997. Admitted that Copaxone® is sold in a once-daily 20 mg/mL formulation and a three-times weekly 40 mg/mL formulation. The Domestic Defendants lack sufficient knowledge or information as to the remaining allegations of Paragraph 23 and therefore deny those.

24. Copaxone® (glatiramer acetate injection) comprises acetate salts of synthetic polypeptides made up of four naturally occurring amino acids: L-glutamic acid, L-alanine, L-tyrosine, and L-lysine, with a reported average molar fraction of 0.141, 0.427, 0.095, and 0.338, respectively. (*See* Ex. 15 – Copaxone Package Insert, at 3). Other than average molecular weight and amino acid composition, which are specified on the FDA-approved label for Copaxone® (glatiramer acetate injection), the label and other available literature for Copaxone® (glatiramer acetate injection) have historically provided no detailed information about the physicochemical characteristics of the product. (*See* Ex. 16 – FDA Response, at 25).

ANSWER: Admitted that the Prescribing Information for Copaxone® describes the product as comprising acetate salts of synthetic polypeptides made up of four naturally occurring amino acids: L-glutamic acid, L-alanine, L-tyrosine, and L-lysine, with a reported average molar fraction of 0.141, 0.427, 0.095, and 0.338, respectively. Momenta makes no specific allegations as to the exhibits cited in Paragraph 24 and therefore no response is required as to that exhibit. The

Domestic Defendants lack sufficient knowledge or information as to the remaining allegations of Paragraph 24 and therefore deny those.

25. Glatiramer acetate is generally prepared in three discrete steps. (Ex. 16 – FDA Response, at 13 n.44). In a first step, activated forms of the four constituent amino acids are combined and polymerized in the presence of a polymerization initiator, forming an intermediate copolymer (*i.e.*, a chain of the four constituent amino acids). During this initial polymerization step, certain of the functional groups of the amino acids must be shielded by protecting groups to prevent undesirable side reactions. In a second step, the intermediate copolymer formed in the first step is partially depolymerized and deprotected (*i.e.*, the chain is broken into smaller pieces, and one of the protecting groups is removed). A third step completes the deprotection of the amino acid functional groups and purifies the resulting product, glatiramer acetate. This synthetic process results in a complex, heterogeneous product with inherent variability in the composition of the synthetic polypeptides formed, which vary in amino acid sequence and polypeptide length, as well as variability in the polypeptide composition of manufacturing batches. (*See* Ex. 16 – FDA Response, at 11). Copaxone® (glatiramer acetate injection) was the only glatiramer acetate product available on the market for almost twenty years, as the complexity of the product and the lack of understanding of the chemical structure of Copaxone® (glatiramer acetate injection) and structural signatures for key steps in manufacturing glatiramer acetate prevented development of a generic version of glatiramer acetate that would possess adequate sameness to Copaxone® (glatiramer acetate injection). [footnote 5 omitted]

ANSWER: Admitted that Complaint Exhibit 16 at footnote 44 describes the prior art process for manufacturing glatiramer acetate. Momenta makes no specific allegations as to the exhibit cited in Paragraph 25 and therefore no response is required as to that exhibit. The Domestic Defendants lack sufficient knowledge or information as to the remaining allegations of Paragraph 25 and therefore deny those.

Momenta's Development of Glatopa® (glatiramer acetate injection)

26. Momenta was founded in 2001 and is a leader in the analysis, characterization, design, and preparation of complex pharmaceutical products. Momenta has developed innovative approaches to understand the relationship between a compound's chemical structure, its manufacturing process, and its biological function, even in the case of very complicated pharmaceutical products, and then has applied those understandings to prepare complex pharmaceutical products. Among other things, Momenta applies its innovative technology to the development of generic versions of non-biological complex drugs.

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 26 and therefore deny those.

27. Momenta has developed and patented novel ways to manufacture complex pharmaceuticals. Momenta's patented methods were used to develop and gain regulatory approval from the FDA for the first generic version of Copaxone® (glatiramer acetate injection).

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 27 and therefore deny those.

28. Glatopa® (glatiramer acetate injection) was developed and commercialized in collaboration with Sandoz, and was the first FDA-approved generic version of Copaxone® (glatiramer acetate injection).

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 28 and therefore deny those.

29. Glatopa® (glatiramer acetate injection) 20 mg/mL is a therapeutically equivalent ("AP" rated) fully substitutable version of Teva's daily Copaxone® (glatiramer acetate injection) 20 mg/mL product. Glatopa® (glatiramer acetate injection) 40 mg/mL is an "AP" rated, fully substitutable version of Teva's three-times-per-week Copaxone® (glatiramer acetate injection) 40 mg/mL product. Both Glatopa® (glatiramer acetate injection) 20 mg/mL and Glatopa® (glatiramer acetate injection) 40 mg/mL are indicated for the treatment of patients with relapsing forms of multiple sclerosis. (Ex. 18 – Glatopa® Package Insert).

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 29 and therefore deny those.

30. The discovery of Momenta's patented inventions, which are described and claimed in the patents-in-suit, required years of intense laboratory work. Momenta began its research program seeking methods for the consistent and controlled preparation of glatiramer acetate equivalent to FDA-approved Copaxone® (glatiramer acetate injection) by no later than the beginning of 2006.

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 30 and therefore deny those.

31. Momenta made the unexpected discovery that controlling the glatiramer acetate manufacturing process to produce a specific amino acid derivative (pyro-Glu) within a specific range, measuring the amount of pyro-Glu generated in the manufacturing process, and then selecting batches of glatiramer acetate for further processing based on that pyro-Glu content in that specific range, results in a replicable glatiramer acetate manufacturing process capable of achieving equivalence (e.g., active pharmaceutical ingredient ("API") sameness) to the Copaxone® (glatiramer acetate injection) product.

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 31 and therefore deny those.

32. Momenta also discovered that, unlike the prior art, the manufacturing process of glatiramer acetate could be improved such that generic glatiramer acetate manufacturing could be achieved by including water during the depolymerization step of the manufacturing process. Momenta unexpectedly discovered that the addition of water to the depolymerization step in the glatiramer acetate manufacturing process allowed for the reaction to occur in a controlled manner, resulting in the production of glatiramer acetate that consistently achieved levels of pyro-Glu in the specific range necessary to conform to FDA-approved Copaxone® (glatiramer acetate injection).

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 32 and therefore deny those.

33. Prior to the inventions described and claimed in the patents-in-suit, it was unknown that including water during the depolymerization step and controlling and measuring the pyro-Glu formation as a process step in the manufacture of glatiramer acetate, would result in consistent production of glatiramer acetate API for making a pharmaceutical product equivalent to Copaxone® (glatiramer acetate injection).

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 33 and therefore deny those.

34. After Momenta began research in the area, it entered into a collaboration and license agreement with Sandoz in 2007 regarding the development of a generic glatiramer acetate drug product. Using the methods of manufacture claimed in the patents-in-suit, Momenta worked in collaboration with Sandoz to develop and commercialize Glatopa® (glatiramer acetate injection), a generic form of Teva's Copaxone® (glatiramer acetate injection).

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 34 and therefore deny those.

35. The Abbreviated New Drug Application ("ANDA") for Glatopa® (glatiramer acetate injection) 20 mg/mL, ANDA 090218, was submitted to the FDA in 2007.

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 35 and therefore deny those.

36. In order to be approved by the FDA, a drug product described in an ANDA must be bioequivalent to the reference listed drug ("RLD"), and equivalent in dosage form, strength, route of administration, quality, performance characteristics, and intended use. Section 505(j)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) (requiring that an ANDA provide information to show that the new drug is bioequivalent); 21 C.F.R. § 314.94(a)(6) (requiring that an ANDA provide information to show that the route of administration, dosage form, and strength of the drug product is the same as the RLD); 21 C.F.R. § 320.21(b) (requiring that an ANDA provide evidence of bioequivalence).

ANSWER: Paragraph 36 states legal conclusions to which no answer is required. To the extent that an answer is required, the Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 36 and therefore deny those.

37. In order to be approved by the FDA, the active ingredient(s) in an ANDA product must be "the same as" the reference listed drug product's active ingredient(s). 21 C.F.R. § 314.94(a)(5). Thus, generic applicants must demonstrate to the FDA's satisfaction that the active pharmaceutical ingredient contained in their proposed generic product is "the same as" the active ingredient in the reference listed drug product.

ANSWER: Paragraph 37 states legal conclusions to which no answer is required. To the extent that an answer is required, the Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 37 and therefore deny those.

38. As part of the FDA approval process for Glatopa® (glatiramer acetate injection) 20 mg/mL, the FDA required demonstration that the proposed generic glatiramer acetate active ingredient synthesized by Momenta's manufacturing processes resulted in glatiramer acetate that is the same as the active ingredient in Copaxone® (glatiramer acetate injection), and sufficient information to show that the proposed generic drug product was bioequivalent to Copaxone® (glatiramer acetate injection).

ANSWER: Paragraph 38 states legal conclusions to which no answer is required. To the extent that an answer is required, the Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 38 and therefore deny those.

39. While the Glatopa® (glatiramer acetate injection) 20 mg/mL ANDA was pending, Teva sought to block FDA approval of any ANDA for a generic glatiramer acetate product through a series of Citizen Petitions, arguing, among other things, that their Copaxone® (glatiramer acetate injection) product was too complex to be replicated and requesting heightened sameness criteria. (*See* Ex. 16 – FDA Response, at 1–2). As Teva explained in its Citizen Petitions and the FDA acknowledged, the chemical complexity of glatiramer acetate rendered it incredibly difficult to evaluate whether a generic glatiramer acetate was the same as the active ingredient of Copaxone® (glatiramer acetate injection), and equally difficult to ensure that the manufacturing process for generic glatiramer acetate would reliably result in glatiramer acetate that was the same as Copaxone® (glatiramer acetate injection). *See id*. at 1–3, 11. Indeed, Teva argued that no ANDA applicant could demonstrate "that the active ingredient in the purported generic is the same as that in [Copaxone® (glatiramer acetate injection)]." (Ex. 23 – Teva First Citizen Petition, at 17–18). As Teva explained (*see id*.):

> The unique complexity of Copaxone® makes such a demonstration impossible. Unlike most small-molecule drugs, the active ingredient in Copaxone®—glatiramer acetate—is a complex mixture of polypeptides that contains a huge, perhaps incalculable number of epitopes. At this time, even the most sophisticated chemical analytical tests, including multidimensional analysis, cannot identify and characterize each of the active amino acid sequences that make up glatiramer acetate.

ANSWER: Admitted the quotations in Paragraph 39 appear in the cited exhibits. Admitted that Teva filed several Citizen Petitions. The Domestic Defendants lack sufficient knowledge or information as to the remaining allegations of Paragraph 39 and therefore deny those.

40. Yet Momenta discovered methods that Teva said were "impossible": methods that reliably produced glatiramer acetate that was the same as the active ingredient in Teva's Copaxone® (glatiramer acetate injection). In doing so, Momenta submitted to the FDA extensive physiochemical, biological, and immunological characterization via *more than 60 methods*. (*See* Ex. 57 – Bell 2018, at 3). Through its extensive characterization of the glatiramer acetate in Glatopa® and in Copaxone® (glatiramer acetate injection), Momenta discovered several "structural signatures" for glatiramer acetate which could be incorporated into manufacturing process steps to ensure that the resulting product was the same as the active ingredient in Copaxone® (glatiramer acetate injection). Identifying

these structural signatures was not easy. Because of the "inherent variability" of glatiramer acetate, (*see* Ex. 16 – FDA Response, at 11), even aspects of the substance that are said to be "conserved" from batch to batch nonetheless vary to some degree. *Id*. at 11 n.38.

ANSWER: Admitted that the cited exhibits include the quoted language. Otherwise, The Domestic Defendants lack sufficient knowledge or information as to the remaining allegations of Paragraph 40 and therefore deny those.

41. One of these structural signatures discovered by Momenta was the pyro-Glu concentration of glatiramer acetate. As discussed in more detail below, Momenta discovered that the pyro-Glu concentration served as an important structural signature for the depolymerization step of the manufacturing process for glatiramer acetate, and the FDA agreed. Therefore along with other structural signatures for the manufacturing process as a whole, comparison of pyro-Glu concentration in batches of generic glatiramer acetate with the pyro-Glu concentration of Copaxone® (glatiramer acetate injection) was important to show "sameness" between generic glatiramer acetate and Copaxone® (glatiramer acetate injection). Indeed, Momenta demonstrated to the FDA that the pyro-Glu concentration of the glatiramer acetate in Glatopa® (glatiramer acetate injection) matched that of the glatiramer acetate in Copaxone® (glatiramer acetate injection).

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 41 and therefore deny those.

42. After Momenta submitted this and other evidence, once-daily Glatopa® (glatiramer acetate injection) 20 mg/mL product was approved in April 2015 as the first generic glatiramer acetate product in the United States. On April 16, 2015, the same day that the FDA approved the Glatopa® (glatiramer acetate injection) 20 mg/mL ANDA, the FDA denied all eight of Teva's Citizen Petitions in a public response setting forth the FDA's approach to the review and evaluation of proposed glatiramer acetate ANDAs referencing Teva's Copaxone® (glatiramer acetate injection). *See id*. The FDA required, among other things, that generic glatiramer acetate applicants demonstrate equivalence of the "[s]tructural signatures for polymerization and depolymerization" between any proposed generic glatiramer acetate and the active ingredient of Copaxone® (glatiramer acetate injection), one of these structural signatures for the depolymerization step being, as Momenta had discovered, the concentration of pyro-Glu. *Id*. at 18 n.61, 21, 28. The FDA later published draft guidance providing "recommendations for the development of generic product of glatiramer acetate injection." (*See* Ex. 19 – Draft FDA Guidance at 1). The draft guidance is consistent with the approach described in the CP Response and directs readers to the CP Response for "more detailed discussion." *Id*. at 1 n.1. [footnote 6 omitted]

ANSWER: Admitted that the quotations in Paragraph 42 appear in the cited exhibits. Admitted that the FDA's website lists April 16, 2015 as the approval date for once-daily Glatopa® (glatiramer acetate injection) 20 mg/mL product. The Domestic Defendants lack sufficient knowledge or information as to the remaining allegations of Paragraph 42 and therefore deny those.

43. The ANDA for Glatopa® (glatiramer acetate injection) 40 mg/mL, ANDA 206921, covering a three-times-weekly glatiramer acetate formulation at a dose of 40 mg/mL, was submitted to the FDA on February 14, 2014. On February 13, 2018, the FDA approved the ANDA for Glatopa® (glatiramer acetate injection) 40 mg/mL.

ANSWER: Admitted that the FDA's website lists an approval date of February 13, 2018 for ANDA 206921 for Glatopa® (glatiramer acetate injection) 40 mg/mL. The Domestic Defendants lack sufficient knowledge or information as to the remaining allegations of Paragraph 43 and therefore deny those.

Mylan's Glatiramer Acetate Product

44. The accused products in this litigation are generic glatiramer acetate products. Upon information and belief, MPI filed ANDAs for Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL, generic versions of Teva's Copaxone® (glatiramer acetate injection) Products. (Ex. 20 – ANDA 091646 Approval Letter; Ex. 21 ANDA 206936 approval letter). MPI filed ANDA 091646 for a generic version of Copaxone® (glatiramer acetate injection) 20 mg/mL on June 29, 2009. (*See Teva Pharms.*, 876 F. Supp. 2d at 307–08; Ex. 22 – 2009.09.14 Press Release; Ex. 20 – ANDA 091646 approval letter). Mylan Inc. announced that MPI's ANDA 091646 for the 20 mg/mL form of its generic glatiramer acetate product was accepted for filing by the FDA on September 14, 2009. (Ex. 22 – 2009.09.14 Press Release).

ANSWER: Admitted that MPI filed ANDAs for MPI's GA Products. Admitted that MPI filed ANDA 091646 seeking approval for a generic version of Copaxone® (glatiramer acetate injection) 20 mg/mL on June 29, 2009. Admitted that MPI's ANDA 091646 for the 20 mg/mL form of its generic glatiramer acetate product was accepted for filing by the FDA on September 10, 2009. Momenta makes no specific allegations as to the exhibits cited in Paragraph 44 and therefore no

response is required as to those exhibits. The Domestic Defendants deny the remaining allegations set forth in Paragraph 44.

45. MPI filed ANDA 206936 for a generic version of Copaxone® (glatiramer acetate injection) 40 mg/mL, which was accepted for review by the FDA on February 12, 2014. (Ex. 24 – 2014.08.28 Press Release; Ex. 21 – ANDA 206936 approval letter). Mylan Inc. announced that its ANDA for the 40 mg/mL version was accepted for filing on August 28, 2014. (Ex. 24 – 2014.08.28 Press Release).

ANSWER: Admitted that MPI filed ANDA 206936 for a generic version of Copaxone® (glatiramer acetate injection) 40 mg/mL on February 12, 2014. Admitted that the FDA accepted ANDA No. 206936 for filing on August 11, 2014. Momenta makes no specific allegations as to the exhibits cited in Paragraph 45 and therefore no response is required as to those exhibits. The Domestic Defendants deny the remaining allegations set forth in Paragraph 45.

46. On October 3, 2017, Mylan N.V. (now Viatris, as discussed below) announced that both of its glatiramer acetate ANDAs had received approval by the FDA. (Ex. 25 – 2017.10.03 Mylan Press Release).

ANSWER: Admitted that on October 3, 2017, MPI announced that MPI's GA Products had been approved by the FDA. Momenta makes no specific allegations as to the exhibit cited in Paragraph 46 and therefore no response is required as to that exhibit. The Domestic Defendants deny any remaining allegations set forth in Paragraph 46.

47. On October 4, 2017, Mylan N.V. (now Viatris, as discussed below) announced that it had begun shipping Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL to customers in the United States. (Ex. 26 – 2017.10.04 Mylan Press Release).

ANSWER: Admitted that on October 4, 2017, MPI announced that it had begun shipping MPI's GA Products to customers in the United States. Momenta makes no specific allegations as to the exhibit cited in Paragraph 47 and therefore no response is required as to that exhibit. The Domestic Defendants deny any remaining allegations set forth in Paragraph 47.

48. Upon information and belief, Mylan imports, imports for sale, and sells after importation, glatiramer acetate products containing glatiramer acetate supplied by Natco and/or Gland and made, produced, and/or processed under, or by means of, processes that infringe the patents-in-suit.

ANSWER: Denied**.**

49. Mylan Inc. publicly announced in 2008 that it has an agreement with Natco for Natco to provide glatiramer acetate API for Mylan's Glatiramer Acetate Products in the U.S. market. (Ex. 27 – 2008.06.10 Mylan Press Release; Ex. 29 – Hindu Article; Ex. 45 – Money Control News Article Regarding Natco).

ANSWER: Admitted that Natco manufactures the active pharmaceutical ingredient in MPI's GA Products in India pursuant to an agreement. Momenta makes no specific allegations as to the exhibits cited in Paragraph 49 and therefore no response is required as to those exhibits. The Domestic Defendants deny any remaining allegations set forth in Paragraph 49.

50. Upon information and belief, Natco manufactures, sells for importation, imports, and/or sells after importation glatiramer acetate API, and products containing the same, made, produced, and/or processed under, or by means of, processes that infringe the patents-in-suit.

ANSWER: Paragraph 50 relates only to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants deny all allegations set forth in Paragraph 50.

51. Natco manufactures a number of pharmaceutical products, and is registered with the FDA. (Ex. 28 – Natco Pharma FDA Registration).

ANSWER: The Domestic Defendants are without sufficient knowledge or information as to the allegations of Paragraph 51 and therefore deny those.

52. Mylan Inc. entered into a license and supply agreement with Natco, which granted Mylan Inc. exclusive distribution rights for glatiramer acetate prefilled syringes in the United States and all major markets in Europe, Australia, New Zealand, Japan, and Canada. (Ex. 27 – 2008.06.10 Mylan Press Release). The agreement also includes an option to potentially expand into additional territories. *Id*.

ANSWER: Admitted that Natco manufactures the active pharmaceutical ingredient in MPI's GA Products in India pursuant to an agreement. Admitted that MPI markets MPI's GA Products in the United States. Momenta makes no specific allegations as to the exhibit cited in Paragraph 52 and therefore no response is required as to that exhibit. The Domestic Defendants deny any remaining allegations set forth in Paragraph 52.

53. Upon information and belief, pursuant to the license and supply agreement with Mylan Inc., Natco is working with Mylan to manufacture glatiramer acetate for the U.S. market and is importing and/or selling for importation into the United States glatiramer acetate to Mylan. A June 19, 2015, article stated as follows:

> A senior official of Natco told PTI that they have submitted all the information to [the] FDA with regard to the generic version of Copaxone (Glatiramer Acetate) which is used in the treatment of relapsing-remitting multiple sclerosis. "We have done everything from our side. Once approval comes, we are ready to launch the product. We manufacture the drug and Mylan will market it," the official said.

(Ex. 29 – Hindu Article).

ANSWER: Admitted that Natco manufactures the active pharmaceutical ingredient in MPI's GA Products in India pursuant to an agreement. Admitted that MPI markets MPI's GA Products in the United States. Admitted that MPI imports MPI's GA Products into the United States. Admitted that Paragraph 53 quotes a portion of the cited document. The Domestic Defendants deny any remaining allegations set forth in Paragraph 53.

54. On October 5, 2017, Natco announced that "its marketing partner Mylan N.V., has launched in the U.S the first Glatiramer Acetate Injection 40 mg/mL ... as well as Glatiramer Acetate Injection 20 mg/mL." (Ex. 30 – 2017.10.05 Natco Press Release). In November 2019, Mylan N.V. and Pfizer Inc. announced the merger of Mylan and Upjohn, a division of Pfizer, and the renaming of the newly formed company as Viatris Inc. (Ex. 31 – 2019.11.12 Mylan press release). The merger was completed a year later, in November 2020. (Ex. 32 – 2020.11.16 Pfizer Press Release).

ANSWER: Admitted that the quotations in Paragraph 54 appear in the cited exhibits. Admitted that Mylan merged with Upjohn to create a new company, Viatris. The Domestic Defendants deny the remaining allegations set forth in Paragraph 54.

55. Today, Viatris markets and/or advertises Mylan's Glatiramer Acetate Products via the website www.glatirameracetate.com. (Ex. 33 – Viatris Glatiramer Acetate Website). For example, Viatris advertises a "Viatris Advocate" service that is a "patient support program to help [patients] access [glatiramer acetate] therapy as soon as possible." (Ex. 34 – Viatris Advocate Brochure). Viatris also offers, *e.g.*, a co-pay assistance program that allows patients' "co-pay[s] for VIATRIS' Glatiramer Acetate Injection [to be] as low as $0 a month." *Id*.

ANSWER: The website www.glatirameracetate.com speaks for itself. Admitted that the quotations in Paragraph 55 appear in the cited exhibits. The Domestic Defendants deny the remaining allegations of Paragraph 55.

56. The logo used to market Mylan's Glatiramer Acetate Products is a registered trademark of "Mylan Pharmaceuticals Inc., a Viatris Company." (Ex. 33 – Viatris Glatiramer Acetate Website). To register that trademark, upon information and belief, MPI certified to the United States Patent and Trademark Office that it had used or intended to use the trademark in commerce. *See, e.g.*, 15 U.S.C. § 1051.

ANSWER: Admitted that the logo used to market MPI's GA Products is a registered trademark of MPI. The rest of Paragraph 56 contains legal conclusions or allegations to which no answer is required. To the extent a response is required, denied.

57. Upon information and belief, glatiramer acetate manufactured by Natco has been imported into the United States. Upon information and belief, Natco, working with Mylan, has exported glatiramer acetate products from India, for commercial sale of glatiramer acetate products in the United States. (Ex. 35 – *Teva Pharms. USA, Inc. et al. v. Mylan Pharms. Inc., et al.*, 1:14-cv-01278 (D. Del.), ECF No. 1 at ¶ 37).

ANSWER: Admitted that MPI has imported into the United States MPI's GA Products. The Domestic Defendants deny the allegations set forth in Paragraph 57.

58. International shipping documents reveal that Natco has shipped glatiramer acetate products from India to Mylan in the United States. For example, those documents reveal that Natco has repeatedly shipped glatiramer acetate products to Kelly Jo Cox, an MPI employee, in Philadelphia, Pennsylvania. (Ex. 36 – 2018.12.06 Bill of Lading; Ex. 59 – Customs Ruling; see also Ex. 60 – 2018.05.09 Bill of Lading; Ex. 61 – 2018.01.02 Bill of Lading). Natco has also shipped glatiramer acetate products to MPI in Atlanta, Georgia. (Ex. 62 – 2021.09.28 Bill of Lading).

ANSWER: Denied.

59. Upon information and belief, glatiramer acetate products manufactured by Natco have also been shipped to Mylan Teoranta in Ireland, which in turn has shipped glatiramer acetate products to MPI in the United States. (Ex. 63 – 2021.09.30 Bill of Lading; Ex. 37 – Mylan Teoranta Shipping Records).

ANSWER: Denied.

60. Upon information and belief, Mylan Teoranta manufactures Mylan Glatiramer Acetate Products, made by a process that infringes the patents-in-suit, for distribution and sale by MPI throughout the United States and in this judicial District. The approved label for Mylan's 40 mg/mL Glatiramer Acetate Injection states that it is manufactured by Mylan Institutional in Galway, Ireland for MPI. (Ex. 38 – Mylan 40mg/mL label, at 16). There have also been shipments of glatiramer acetate products from Mylan Teoranta in Ireland to MPI in the United States, involving quantities of product greater than that necessary for regulatory approval. (Ex. 37 – Mylan Teoranta Shipping Records). [footnote 7 omitted]

ANSWER: Admitted that Mylan Teoranta provides fill and finish services for MPI's 40 mg GA Products. Admitted that the FDA-approved prescribing information for MPI's 40 mg GA Products states that the product is manufactured by Mylan Institutional, Galway, Ireland. Admitted that Mylan Teoranta does business under the d/b/a name Mylan Institutional. Momenta makes no specific allegations as to the exhibits cited in Paragraph 60 and therefore no response is required as to those exhibits. The Domestic Defendants deny all remaining allegations set forth in Paragraph 60.

61. Upon information and belief, Mylan Teoranta is a subsidiary of Viatris. (Ex. 11 – Viatris Form 10-K 2022, at 163).

ANSWER: Admitted that Mylan Teoranta is an independently-operated subsidiary of Viatris. Momenta makes no specific allegations as to the exhibit cited in Paragraph 61 and therefore no response is required as to that exhibit.

62. Upon information and belief, Mylan and/or Natco also sold for importation and/or imported glatiramer acetate products to prepare for the commercial launch of its Glatiramer Acetate Products, including engaging in activities not covered by the safe harbor of 35 U.S.C. § 271(e)(1). As noted above, there have been shipments of glatiramer acetate products from India to the United States following Mylan's receipt of regulatory approval in the United States and in amounts greater than necessary for regulatory approval. (*See* Ex. 36 – 2018.12.06 Bill of Lading; Ex. 59 – Customs Ruling; *see also* Ex. 60 – 2018.05.09 Bill of Lading; Ex. 61 – 2018.01.02 Bill of Lading; Ex. 62 – 2021.09.28 Bill of Lading).

ANSWER: Admitted that MPI has imported MPI's GA Products into the United States. Momenta makes no specific allegations as to the exhibits cited in Paragraph 62 and therefore no response is required as to those exhibits. The Domestic Defendants deny the remaining allegations set forth in Paragraph 62.

63. Upon information and belief, Gland manufactures Mylan Glatiramer Acetate Products made by a process that infringes the patents-in-suit, for distribution and sale by MPI throughout the United States and in this judicial District. The approved label for Mylan's 20 mg/mL Glatiramer Acetate Injection states that it is manufactured by Gland in India. (Ex. 39 – Mylan 20mg/mL label, at 15). Upon information and belief, Gland provides fill-finish services to Mylan, manufacturing pre-filled syringes containing glatiramer acetate supplied by Natco.

ANSWER: Admitted that Gland provides fill and finish services for MPI's 20 mg GA Products. Admitted that the FDA-approved prescribing information for MPI's 20 mg GA Products states that the product is manufactured by Gland Pharma Ltd, Hyderabad 500 043, India and that the product is manufactured for Mylan Pharmaceuticals Inc., Morgantown, WV 26505. Momenta makes no specific allegations as to the exhibit cited in Paragraph 63 and therefore no response is required as to that exhibit. The Domestic Defendants deny the remaining allegations set forth in Paragraph 63.

64. Upon information and belief, Gland manufactures, sells for importation, and/or imports glatiramer acetate products made, produced, and/or processed under, or by means of, processes that infringe the patents-in-suit.

ANSWER: Denied.

65. Gland manufactures a number of pharmaceutical products, and is registered with the FDA. (Ex. 14 – Gland Corporate Brochure).

ANSWER: The Domestic Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 65 and therefore deny those allegations.

66. Upon information and belief, both the 20 mg/mL and 40 mg/mL forms of the Mylan Glatiramer Acetate Product are believed to be made by a process that infringes the claims of the patents-in-suit.

ANSWER: Denied.

67. Upon information and belief, in order for the FDA to have approved Defendants' manufacture of generic glatiramer acetate, Mylan along with Mylan Teoranta, Gland and Natco will have included in their process for manufacturing batches of glatiramer acetate for commercial sale: (1) a method of manufacturing glatiramer acetate containing 2000–7000 ppm pyro-Glu by water-mediated control of the depolymerization step, which method infringes the '489 Patent; and (2) a method of manufacturing glatiramer acetate containing 2000–7000 ppm pyro-Glu, which method controlled and measured the pyro-Glu level as part of the manufacturing process, and which infringes the '374 Patent.

ANSWER: Denied.

68. Upon information and belief, Defendants have knowledge of both the '374 and '489 patents. Upon information and belief, Mylan has filed and/or has knowledge of Oppositions to several of Momenta's European patents in the same families as the '374 and '489 patents.

ANSWER: Denied that Viatris, Mylan Inc. or MPI filed oppositions to Momenta's European patents in the same families as the '374 and '489 patents. The Domestic Defendants deny the remaining allegations of Paragraph 68.

69. For example, on September 14, 2014, Generics [UK] Ltd. ("trading as Mylan") filed an opposition to Momenta's European Patent No. 2,277,050, which claims priority to the same provisional applications to which the '374 patent claims priority and shares a common disclosure with the '374 patent. (*See* Ex. 54 – Generics Notice of Opposition).

ANSWER: Exhibit 54 speaks for itself but that otherwise the allegations of Paragraph 69 are denied. Admitted that the quotations in Paragraph 42 appear in the cited exhibits. Momenta makes no specific allegations as to the exhibit cited in Paragraph 69 and therefore no response is required as to that exhibit.

70. In addition, upon information and belief, Mylan filed an Opposition to Momenta's European Patent No. 2,414,384 (the "'384 Patent"), which claims priority to the same provisional applications to which the '489 Patent claims priority and shares a common disclosure with the '489 Patent. Specifically, the '384 Patent has been opposed by an entity represented by Gill Jennings & Every LLP ("GJE"). (*See* Ex. 65 – Notice of Representation by GJE). GJE has represented Mylan in connection with the Opposition filed to the '050 Patent. (*See* Ex. 66 – GJE Notice of Appeal). Indeed, other filings in the Opposition proceedings for the '384 Patent have explicitly referred to Mylan's involvement in those proceedings. (*See* Ex. 67 – Synthon Reply, at ¶¶ 99, 124). In addition, Synthon B.V. filed an Opposition to the '384 Patent. (*See* Ex. 53 – Synthon Notice of Opposition). Upon information and belief, Mylan N.V. (now Viatris) partnered with Synthon B.V. to develop and/or market glatiramer acetate in Europe, and therefore Synthon and Mylan have worked in concert in, or at a minimum kept each other apprised of, their EU oppositions related to glatiramer acetate. (*See* Ex. 55 – 2017.10.05 Mylan Press Release; Ex. 56 – 2020.09.16 Mylan Press Release).

ANSWER: The documents cited in Paragraph 70 speak for themselves. Otherwise, the Domestic Defendants deny the allegations set forth in Paragraph 70. Momenta makes no specific allegations as to the exhibits cited in Paragraph 4 and therefore no response is required as to those exhibits.

71. In addition, upon information and belief, Mylan has informed Mylan Teoranta, Natco, and Gland of the EU Opposition activity related to Momenta's European patents, given their joint development and/or commercialization of glatiramer acetate, and thus all Defendants have knowledge of the '374 Patent and '489 Patents families, which include the '374 Patent and the '489 Patent.

ANSWER: Denied.

JURISDICTION AND VENUE

72. Momenta incorporates by reference paragraphs 1–71.

ANSWER: The Domestic Defendants incorporate fully by reference their answers to Paragraphs 1-71.

A. Subject Matter Jurisdiction

73. This is a civil action for infringement of two United States patents, arising under the Patent Laws of the United States, including 35 U.S.C. § 271 *et seq*..

ANSWER: Paragraph 73 states legal conclusions and allegations to which no answer is required. To the extent that an answer is required, the Domestic Defendants do not contest that this action for patent infringement arises under 35 U.S.C. § 271 *et seq*. The Domestic Defendants deny any remaining allegation set forth in Paragraph 73.

74. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 74 states legal conclusions and allegations to which no answer is required. To the extent that an answer is required, admitted that the Complaint purports to be an action arising under 28 U.S.C. §§ 1331 and 1338(a). The Domestic Defendants deny the remaining allegations set forth in Paragraph 74.

B. Personal Jurisdiction

75. This Court has personal jurisdiction over Defendants because, as discussed below, Defendants reside in Pennsylvania, transact business in Pennsylvania, contract to supply services or things in Pennsylvania, have committed acts constituting patent infringement (or inducement thereof) in Pennsylvania, and/or have caused harm to Momenta in Pennsylvania.

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, it is not contested that the Court has personal jurisdiction over Viatris, Mylan Inc. and MPI for purposes of this litigation only. The Domestic Defendants deny the remaining allegations of Paragraph 75.

76. Upon information and belief, Defendants work in concert with one another to make, use, offer to sell, and sell generic glatiramer acetate products throughout the United States, including in Pennsylvania.

ANSWER: Denied.

77. Momenta receives royalties from the sale of Glatopa® (glatiramer acetate injection) products in the Commonwealth of Pennsylvania.

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 77 and therefore deny those.

78. Upon information and belief, as a result of Defendants' marketing, selling, or offering for sale of the Mylan Glatiramer Acetate Products in the Commonwealth of Pennsylvania, Momenta has lost royalties and profit from the loss of sales of Glatopa® (glatiramer acetate injection) products and has been injured in the Commonwealth of Pennsylvania.

ANSWER: The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 78 and therefore deny those.

79. Upon information and belief, Defendants, either each alone and/or together with one another as affiliates and/or agents, have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(a)–(c) and/or (g) that has led and/or will lead to foreseeable harm and injury to Momenta in Pennsylvania.

ANSWER: Denied.

Defendant Mylan

80. Upon information and belief, MPI is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Pennsylvania and throughout the United States.

ANSWER: Admitted that MPI is a pharmaceutical company that develops, manufactures, and distributes certain pharmaceutical products in the United States. The Domestic Defendants deny the remaining allegations of Paragraph 80.

81. This Court has specific personal jurisdiction over MPI pursuant to due process and/or the Pennsylvania Long Arm Statute by virtue of the fact that, *inter alia*, MPI has committed or induced tortious acts of patent infringement under 35 U.S.C. § 271 in Pennsylvania, and intends a future course of conduct that includes committing or inducing acts of patent infringement in Pennsylvania. These acts have led and will lead to foreseeable harm and injury to Momenta in Pennsylvania.

ANSWER: Paragraph 81 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, and for purposes of this litigation only, it is not contested that this Court, the Western District of Pennsylvania, has personal jurisdiction over MPI. The Domestic Defendants deny the remaining allegations of Paragraph 81.

82. For example, upon information and belief, MPI conducts business in Pennsylvania, by at least offering for sale, importing, and/or selling Mylan Glatiramer Acetate Products, which are made by the claimed inventions of the Patents-in-Suit, in Pennsylvania. For example, upon information and belief, MPI imports generic glatiramer acetate made by the claimed inventions of the Patents-in-Suit into Pennsylvania. (Ex. 52 –2018.12.29 Bill of Lading; Ex. 36 – 2018.12.06 Bill of Lading; Ex. 59 – Customs Ruling; *see also* Ex. 60 – 2018.05.09 Bill of Lading; Ex. 61 – 2018.01.02 Bill of Lading).

ANSWER: Denied.

83. Upon information and belief, MPI conducts substantial business in the Commonwealth of Pennsylvania and this judicial District, including at least regularly doing and soliciting business at its Austin, Pennsylvania facilities, and engaging in persistent conduct and/or deriving substantial revenue from goods and services provided to customers in the Commonwealth of Pennsylvania, including in the Western District of Pennsylvania.

ANSWER: Paragraph 83 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, and for purposes of this litigation only, it is not contested that this Court, the Western District of Pennsylvania, has personal jurisdiction over MPI. The Domestic Defendants deny the remaining allegations of Paragraph 83.

84. Upon information and belief, MPI has previously actively litigated in this jurisdiction. *See, e.g.*, *Amgen Inc. v. Mylan Inc.*, No. 2-17-cv-01235 (W.D. Pa.).

ANSWER: Paragraph 84 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, and for purposes of this litigation only, it is not contested that this Court, the Western District of Pennsylvania, has personal jurisdiction over MPI. The Domestic Defendants deny the remaining allegations of Paragraph 84.

85. Personal jurisdiction also exists over MPI because MPI has additional substantial, continuous and systematic contacts with Pennsylvania, including, among other things, registration as an entity doing business in Pennsylvania, employment of officers based in Pennsylvania, appointment of a registered agent in Pennsylvania for service of process, and registration as a manufacturer and wholesale distributor of drugs in Pennsylvania.

ANSWER: Paragraph 85 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required and for purposes of this litigation only, it is not contested that this Court, the Western District of Pennsylvania, has personal jurisdiction over MPI. The Domestic Defendants deny the remaining allegations of Paragraph 85.

86. Upon information and belief, MPI is a wholly owned subsidiary of Mylan Inc., which exercises considerable control over MPI. *See Merck Sharp & Dohme B.V. et al. v. Mylan Pharms Inc. et al.*, No. 1:20-cv-00061-JPB, ECF No. 20, ¶ 7.

ANSWER: Admitted that MPI is an independently operated, indirectly wholly owned subsidiary of Mylan Inc. The Domestic Defendants deny any remaining allegations set forth in Paragraph 86.

87. Upon information and belief, Mylan Inc., directly or through MPI is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Pennsylvania and throughout the United States.

ANSWER: Admitted that MPI is a pharmaceutical company that develops, manufactures, and distributes certain pharmaceutical products in the United States. The Domestic Defendants deny the remaining allegations of Paragraph 87.

88. This Court has general personal jurisdiction over Mylan Inc. because, inter alia, Mylan Inc. is an entity organized under the laws of Pennsylvania; maintains its principal place of business in Canonsburg, Pennsylvania; Mylan Inc. has availed itself of the rights and benefits of Pennsylvania law; and has engaged in substantial and continuing contacts with Pennsylvania.

ANSWER: Paragraph 88 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, and for purposes of this litigation only, it is not contested that this Court, the Western District of Pennsylvania, has personal jurisdiction over Mylan Inc. The Domestic Defendants deny the remaining allegations of Paragraph 88.

89. In addition, upon information and belief, Mylan Inc. alone and/or together with its affiliate and/or agent MPI has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271 that has led and/or will lead to foreseeable harm and injury to Momenta in Pennsylvania.

ANSWER: Denied.

90. Upon information and belief, Mylan, Inc. is a wholly owned subsidiary of Viatris, which exercises considerable control over Mylan, Inc. (Ex. 11 – Viatris Inc. Form 10-K, 2022 at 165).

ANSWER: Admitted that Mylan Inc. is an independently operated, indirectly wholly-owned subsidiary of Viatris. Momenta makes no specific allegations as to the exhibit cited in Paragraph 90 and therefore no response is required as to that exhibit. The Domestic Defendants deny the remaining allegations set forth in Paragraph 90.

91. This Court has general personal jurisdiction over Viatris because, inter alia, Viatris maintains its principal place of business in Canonsburg, Pennsylvania, has availed itself of the rights and benefits of Pennsylvania law, and has engaged in substantial and continuing contacts with Pennsylvania. In addition, Viatris, alone and/or together with its affiliates Mylan Inc. and MPI, has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271 that has led and/or will lead to foreseeable harm and injury to Momenta in Pennsylvania.

ANSWER: Paragraph 91 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, and for purposes of this litigation only, it is not

contested that this Court, the Western District of Pennsylvania, has personal jurisdiction over Viatris. The Domestic Defendants deny the remaining allegations of Paragraph 91.

92. Upon information and belief, MPI, Mylan Inc., and Viatris hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity for purposes of manufacturing, selling, marketing, distribution and importation of generic drug products in Pennsylvania and throughout the United States.

ANSWER: Denied.

93. Upon information and belief, MPI, Mylan Inc., and Viatris Inc. are agents of each other with respect to formulating, manufacturing, packaging, importing, marketing and/or selling pharmaceutical products throughout the United States and with respect to Mylan's Glatiramer Acetate Products.

ANSWER: Denied.

94. Upon information and belief, MPI, Mylan Inc., and Viatris Inc. are acting in concert with each other with respect to formulating, manufacturing, packaging, importing, marketing and/or selling pharmaceutical products throughout the United States and with respect to Mylan's Glatiramer Acetate Products.

ANSWER: Denied.

Defendant Mylan Teoranta

95. This Court has specific personal jurisdiction over Mylan Teoranta pursuant to due process and/or the Pennsylvania Long Arm Statute by virtue of the fact that, *inter alia*, Mylan Teoranta has committed or induced tortious acts of patent infringement under 35 U.S.C. § 271 in Pennsylvania and intends a future course of conduct that includes committing or inducing acts of patent infringement in Pennsylvania. Alternatively, personal jurisdiction also exists over foreign defendant Mylan Teoranta because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met.

ANSWER: Paragraph 95 contains legal conclusions and allegations to which no answer is required. To the extent a response is required, Paragraph 95 relates to Mylan Teoranta. Mylan Teoranta has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants deny the allegations set forth in Paragraph 95.

96. Upon information and belief, Mylan Teoranta partners with Viatris, Mylan Inc., and MPI to manufacture and market generic glatiramer acetate products in the United States, including in this District. (*See, e.g.*, Ex. 38 – Mylan 40mg/mL label 16; Ex. 10 – Irish Times Article).

ANSWER: Admitted that Mylan Teoranta provides fill and finish services for MPI's 40 mg GA Products in Ireland. Momenta makes no specific allegations as to the exhibit cited in Paragraph 96 and therefore no response is required as to that exhibit. The Domestic Defendants deny the remaining allegations set forth in Paragraph 96.

97. Upon information and belief, Mylan Teoranta has engaged in and maintained systematic and continuous business contacts within the Commonwealth of Pennsylvania and has purposefully availed itself of the benefits and protections of the laws of Pennsylvania.

ANSWER: Paragraph 97 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 97 relates to Mylan Teoranta. Mylan Teoranta has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants deny the allegations set forth in Paragraph 97.

98. Upon information and belief, Mylan Teoranta has filed ANDAs with the FDA and has marketed generic pharmaceutical products in the Commonwealth of Pennsylvania, including, *inter alia*, levoleucovorin calcium.

ANSWER: Paragraph 98 relates to Mylan Teoranta. Mylan Teoranta has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. Admitted that Mylan Teoranta has filed ANDAs with the FDA for products unrelated to MPI's GA Products. Admitted that Mylan Teoranta previously marketed a levoleucovorin calcium product, a product that is now discontinued. The Domestic Defendants deny the remaining allegations set forth in Paragraph 98.

99. Upon information and belief, Mylan Teoranta has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the Commonwealth of Pennsylvania, including, *inter alia*, levoleucovorin calcium.

ANSWER: Paragraph 99 relates to Mylan Teoranta. Mylan Teoranta has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 99 and therefore deny those.

100. Upon information and belief, Mylan Teoranta formulates Mylan Glatiramer Acetate Products for distribution and sale throughout the United States, including this judicial District, and alone and/or together with its affiliates and/or agents Mylan Teoranta imports, markets, sells, and/or offers for sale said products in the Commonwealth of Pennsylvania.

ANSWER: Admitted that Mylan Teoranta provides fill and finish services for MPI's 40 mg GA Products in Ireland. The Domestic Defendants deny the remaining allegations set forth in Paragraph 100.

101. Upon information and belief, this Court has personal jurisdiction over Mylan Teoranta for the reasons stated herein, including, *inter alia*, Mylan Teoranta's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Mylan Teoranta at home in the forum.

ANSWER: Paragraph 101 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 101 relates to Mylan Teoranta. Mylan Teoranta has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants deny the allegations set forth in Paragraph 101.

102. Alternatively, this Court may exercise personal jurisdiction over Mylan Teoranta under Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Mylan Teoranta is a foreign defendant not subject to personal jurisdiction in any state's courts of general jurisdiction; and (c) Mylan Teoranta has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products like the Mylan Glatiramer Acetate Products that are distributed

throughout the United States, such that this Court's exercise of jurisdiction over Mylan Teoranta satisfies due process.

ANSWER: Paragraph 102 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 102 relates to Mylan Teoranta. Mylan Teoranta has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants deny the allegations set forth in Paragraph 102.

Defendant Natco

103. This Court has specific personal jurisdiction over Natco pursuant to due process and/or the Pennsylvania Long Arm Statute by virtue of the fact that, *inter alia*, Natco has committed or induced tortious acts of patent infringement under 35 U.S.C. § 271 in Pennsylvania, and intends a future course of conduct that includes committing or inducing acts of patent infringement in Pennsylvania. Alternatively, personal jurisdiction also exists over foreign defendant Natco because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met.

ANSWER: Paragraph 103 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 103 relates to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants deny the allegations set forth in Paragraph 103.

104. Upon information and belief, Natco partners with Mylan to manufacture and market generic glatiramer acetate products in the United States, including in this District. (*See* Ex. 27 – 2008.06.10 Mylan Press Release; Ex. 29 – Hindu Article; Ex. 40 – Natco Contract Manufacturing Page; *see also* Ex. 41 – Natco International Formulations Page; Ex. 42 – Natco 2019–20 Annual Report, at 12).

ANSWER: Paragraph 104 contains legal conclusions and allegations to which no answer is required. To the extent a response is required, Paragraph 104 relates to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. Admitted that Natco manufactures the active pharmaceutical ingredient used in MPI's GA

Products in India. Momenta makes no specific allegations as to the exhibits cited in Paragraph 104 and therefore no response is required as to those exhibits. The Domestic Defendants deny the remaining allegations set forth in Paragraph 104.

105. Upon information and belief, Natco has engaged in and maintained systematic and continuous business contacts within the Commonwealth of Pennsylvania, and has purposefully availed itself of the benefits and protections of the laws of Pennsylvania.

ANSWER: Paragraph 105 contains legal conclusions and allegations to which no answer is required. To the extent a response is required, Paragraph 105 relates to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants deny the allegations set forth in Paragraph 105.

106. Upon information and belief, Natco Pharma, Inc. is a wholly-owned subsidiary of Natco Pharma Ltd. (Ex. 43 – Natco 2020-21 Annual Report, at 174). Upon information and belief, Natco Pharma, Inc. is a business located at 241 West Roseville Road, Lancaster, PA 17601. (Ex. 44 – Pennsylvania Department of State Business Entity Report for Natco Pharma, Inc.). Natco has purposefully availed itself of the benefits and protections of the laws of Pennsylvania by maintaining a place of business in Pennsylvania.

ANSWER: Paragraph 106 contains legal conclusions and allegations to which no answer is required. To the extent a response is required, Paragraph 106 relates to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. Momenta makes no specific allegations as to the exhibits cited in Paragraph 106 and therefore no response is required as to those exhibits. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 106 and therefore deny those allegations.

107. Upon information and belief, Natco routinely files Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") and markets dozens of generic pharmaceutical products in the Commonwealth of Pennsylvania, including, *inter alia*, alprazolam, armodafinil, lansoprazole, ondansetron hydrochloride, rizatriptan benzoate, and trihexyphenidyl hydrochloride.

ANSWER: Paragraph 107 relates to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 107 and therefore deny those allegations.

108. Upon information and belief, Natco has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the Commonwealth of Pennsylvania, including, *inter alia*, alprazolam, armodafinil, lansoprazole, ondansetron hydrochloride, rizatriptan benzoate, and trihexyphenidyl hydrochloride.

ANSWER: Paragraph 108 relates to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants deny the allegations set forth in Paragraph 108. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 108 and therefore deny those allegations.

109. Upon information and belief, Natco (including through its business partner Mylan) imports, markets, sells, and/or offers for sale Mylan Glatiramer Acetate Products and/or glatiramer acetate for use in Mylan Glatiramer Acetate Products in the Commonwealth of Pennsylvania. (*See* Ex. 36 – 2018.12.06 Bill of Lading; Ex. 60 – 2018.05.09 Bill of Lading; Ex. 61 – 2018.01.02 Bill of Lading; Ex. 59 – Customs Ruling; *see also* Ex. 27 – 2008.06.10 Mylan Press Release; Ex. 29 – Hindu Article; Ex. 40 – Natco Contract Manufacturing Page; Ex. 41 – Natco International Formulations Page; Ex. 42 – Natco 2019–20 Annual Report, at 12).

ANSWER: Paragraph 109 relates to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. Momenta makes no specific allegations as to the exhibits cited in Paragraph 109 and therefore no response is required as to those exhibits. The Domestic Defendants deny the allegations set forth in Paragraph 109.

110. Upon information and belief, this Court has personal jurisdiction over Natco for the reasons stated herein, including, *inter alia*, Natco's activities in the forum, activities directed at the

forum, and significant contacts with the forum, all of which render Natco at home in the forum.

ANSWER: Paragraph 110 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 110 relates to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 110 and therefore deny those allegations.

111. Alternatively, this Court may exercise personal jurisdiction over Natco under Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Natco is a foreign defendant not subject to personal jurisdiction in any state's courts of general jurisdiction; and (c) Natco has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products like the Mylan Glatiramer Acetate Products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Natco satisfies due process.

ANSWER: Paragraph 111 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 111 relates to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 111 and therefore deny those allegations.

Defendant Gland

112. This Court has specific personal jurisdiction over Gland pursuant to due process and/or the Pennsylvania Long Arm Statute by virtue of the fact that, *inter alia*, Gland has committed or induced tortious acts of patent infringement under 35 U.S.C. § 271 in Pennsylvania and intends a future course of conduct that includes committing or inducing acts of patent infringement in Pennsylvania. Alternatively, personal jurisdiction also exists over foreign defendant Gland because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met.

ANSWER: Paragraph 112 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 112 relates to Gland. Gland has

moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 112 and therefore deny those allegations.

113. Upon information and belief, Gland partners with Mylan to manufacture, import and/or market generic glatiramer acetate products in the United States, including in this District. (*See, e.g.*, Ex. 39 – Mylan 20mg/ml label, at 15; Ex. 45 – Money Control News Article Regarding Natco).

ANSWER: Admitted that Gland provides fill and finish services for MPI's 20 mg GA Products in India. Momenta makes no specific allegations as to the exhibits cited in Paragraph 113 and therefore no response is required as to those exhibits. The Domestic Defendants deny the remaining allegations set forth in Paragraph 113.

114. Upon information and belief, Gland has engaged in and maintained systematic and continuous business contacts within Commonwealth of Pennsylvania and has purposefully availed itself of the benefits and protections of the laws of Pennsylvania.

ANSWER: Paragraph 114 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 114 relates to Gland. Gland has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 114 and therefore deny those allegations.

115. Upon information and belief, Gland has shipped large quantities of pharmaceutical products from India to Philadelphia Regional Port Authority, Philadelphia, Pennsylvania. Gland has purposefully availed itself of the benefits and protections of the laws of Pennsylvania by importing its products into Pennsylvania.

ANSWER: Paragraph 115 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 115 relates to Gland. Gland has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to

state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 115 and therefore deny those allegations.

116. Upon information and belief, Gland files ANDAs and markets generic pharmaceutical products in the Commonwealth of Pennsylvania, including, *inter alia*, magnesium sulfate.

ANSWER: Paragraph 116 relates to Gland. Gland has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 116 and therefore deny those allegations.

117. Upon information and belief, Gland has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the Commonwealth of Pennsylvania, including, *inter alia*, magnesium sulfate.

ANSWER: Paragraph 117 relates to Gland. Gland has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 117 and therefore deny those allegations.

118. Upon information and belief, Gland formulates and/or manufactures Mylan Glatiramer Acetate Products for distribution and sale throughout the United States, including in the Commonwealth of Pennsylvania, and either alone and/or through its business partner Mylan imports, markets, sells, and offers for sale said products in the Commonwealth of Pennsylvania.

ANSWER: Admitted that Gland provides fill and finish services for MPI's 20 mg GA Products in India. The Domestic Defendants deny the remaining allegations set forth in Paragraph 118.

119. Upon information and belief, this Court has personal jurisdiction over Gland for the reasons stated herein, including, inter alia, Gland's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render jurisdiction in this Court proper.

ANSWER: Paragraph 119 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 119 relates to Gland. Gland has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 119 and therefore deny those allegations.

120. Alternatively, this Court may exercise personal jurisdiction over Gland under Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Gland is a foreign defendant not subject to personal jurisdiction in any state's courts of general jurisdiction; and (c) Gland has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products like the Mylan Glatiramer Acetate Products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Gland satisfies due process.

ANSWER: Paragraph 120 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 120 relates to Gland. Gland has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 116 and therefore deny those allegations.

C. Venue

121. Venue is proper in this district pursuant to the provisions of 28 U.S.C. §§ 1391(b) (c), (d) and 1400(b).

ANSWER: Paragraph 121 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, venue over MPI, Mylan Inc., and Viatris is not contested in this Court for purposes of this litigation only. The Domestic Defendants deny the remaining allegations of Paragraph 121.

122. Venue is proper in this district for Viatris, Mylan Inc., and MPI pursuant to the provisions of 28 U.S.C. §§ 1391(b), (c), (d) and 1400(b) because they reside in this District and/or

have a permanent and continuous presence in, have committed acts of infringement in, and maintain regular and established places of businesses in this District.

ANSWER: Paragraph 122 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, venue over MPI, Mylan Inc., and Viatris is not contested in this Court for purposes of this litigation only. The Domestic Defendants deny the remaining allegations of Paragraph 122.

123. By registering to conduct business in Pennsylvania and by having facilities where they regularly conduct business in this District, Viatris, Mylan Inc., and MPI have a permanent and continuous presence and regular and established places of business in the Western District of Pennsylvania.

ANSWER: Paragraph 123 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, venue over MPI, Mylan Inc., and Viatris is not contested in this Court for purposes of this litigation only. The Domestic Defendants deny the remaining allegations of Paragraph 123.

124. Viatris maintains a principal place of business in this District and therefore has a regular and established place of business in the Western District of Pennsylvania for purposes of venue under 28 U.S.C. §1400(b). (*See, e.g.*, Ex. 11 – Viatris Form 10-K).

ANSWER: Paragraph 124 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, venue over Viatris is not contested in this Court for purposes of this litigation only. The Domestic Defendants deny the remaining allegations of Paragraph 124.

125. Viatris has committed acts of direct infringement in this judicial District itself and/or through its wholly owned subsidiaries Mylan Inc. and MPI. For example, upon information and belief, Viatris, itself and/or through its wholly owned subsidiaries Mylan Inc. and MPI, which act as agents and alter egos of Viatris and are completely controlled and dominated by Viatris, performs acts of infringement in this District by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District, including at 1000 Mylan Blvd., Canonsburg, PA 15317. Upon information and belief, Viatris also performs acts in this District constituting inducement of MPI, Mylan Inc.,

Mylan Teoranta, Natco, and/or Gland to perform acts of infringement by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District and elsewhere in the United States.

ANSWER: Denied**.**

126. Mylan Inc. is an entity organized under the laws of Pennsylvania and maintains a principal place of business in this District. (*See* Ex. 6 – Mylan Form S-4). Mylan Inc. therefore resides in the Western District of Pennsylvania for purposes of venue under 28 U.S.C. §1400(b). Mylan has previously conceded that venue is proper in this District for Mylan Inc. as a Pennsylvania corporation. *See Bausch Healthcare Ireland Ltd. et al. v. Mylan Labs Ltd. et al.*, No. 2:21-cv-573-WSH, ECF No. 62-4 at 8 n.5 (W.D. Pa.).

ANSWER: Paragraph 126 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, venue over Mylan Inc. is not contested in this Court for purposes of this litigation only. The Domestic Defendants deny the remaining allegations of Paragraph 126.

127. Mylan Inc. has committed acts of direct infringement in this judicial District itself and/or through its wholly owned subsidiary MPI. For example, upon information and belief, Mylan Inc., itself and/or through its wholly owned subsidiary MPI, which acts as an agent and alter ego of Mylan Inc. and is completely controlled and dominated by Mylan Inc., performs acts of infringement in this District by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District, including at 1000 Mylan Blvd., Canonsburg, PA 15317. Upon information and belief, Mylan Inc. also performs acts in this District constituting inducement of Viatris, MPI, Mylan Teoranta, Natco, and/or Gland to perform acts of infringement by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District and elsewhere in the United States.

ANSWER: Denied**.**

128. Upon information and belief, MPI maintains a regular and established place of business, including office space for its employees and officers, in this District, at 1000 Mylan Blvd., Canonsburg, PA 15317. Mylan has previously conceded that MPI maintains a regular and established place of business in this judicial District. *See Bausch Healthcare Ireland Ltd. et al. v. Mylan Labs Ltd. et al.*, No. 2:21-cv-573-WSH, ECF No. 62-4 at 13 n.7 (W.D. Pa.).

ANSWER: Paragraph 128 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, venue over MPI is not contested in this Court

for purposes of this litigation only. The Domestic Defendants deny the remaining allegations of Paragraph 128.

129. MPI has numerous employees and officers in this judicial District, based at 1000 Mylan Blvd., Canonsburg, PA 15317. Upon information and belief, several of MPI's current officers, including its Secretary, Treasurer, and Director, are based at MPI's Canonsburg, PA location. (Ex. 46 – W.Va. Secretary of State Business Entity Details for MPI). Upon information and belief, MPI also has employment opportunities for its Western District of Pennsylvania location. (See Ex. 47 – MPI Digital Marketing Job Posting; Ex. 64 – MPI Marketing Manager Job Posting). Upon information and belief, the jobs for which MPI has openings would include responsibilities relating to the sale of Mylan Glatiramer Acetate Products, including within this judicial District. (*See id*.).

ANSWER: Paragraph 129 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, venue over MPI is not contested in this Court for purposes of this litigation only. The Domestic Defendants deny the remaining allegations of Paragraph 129.

130. MPI has committed acts of infringement in this judicial District. For example, upon information and belief, MPI is responsible for at least the manufacture, sale, and/or importation of the Mylan Glatiramer Acetate Products. (*See*, *e.g.*, Ex. 38 – Mylan 40mg/mL Label, at 16; Ex. 39 – Mylan 20mg/mL Label, at 15; Ex. 33 – Viatris Glatiramer Acetate Website (noting that the trademark for the Mylan Glatiramer Acetate Products is registered to MPI)). MPI infringes the patents-in-suit in this District by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District, including at 1000 Mylan Blvd., Canonsburg, PA 15317. Upon information and belief, MPI also performs acts in this District constituting inducement of Viatris, Mylan Inc., Mylan Teoranta, Natco, and/or Gland to perform acts of infringement by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District and elsewhere in the United States.

ANSWER: Paragraph 130 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, venue over MPI is not contested in this Court for purposes of this litigation only. The Domestic Defendants deny the remaining allegations of Paragraph 130.

131. Venue is also proper because MPI is a wholly-owned subsidiary of Mylan Inc. and Viatris, operates as an agent and alter-ego of Mylan Inc. and Viatris, and is completely controlled and dominated by Mylan Inc. and Viatris. Viatris and Mylan Inc. direct and are involved in the activities of MPI, and they operate as a single company. As the corporate parents of MPI, Viatris and MPI have participated in the commission of patent infringement in this judicial District, including by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District and elsewhere in the United States that led to foreseeable harm and injury to Momenta in Pennsylvania. Upon information and belief, the officers of MPI are also officers of Viatris and Mylan Inc. For example, John Miraglia, the current Director and Treasurer of MPI, was a signatory to a June 16, 2020 amendment to a Revolving Credit Agreement on behalf of both Mylan Inc and Mylan N.V. (now Viatris). (*See* Ex. 48 at 3.) Thomas Salus, the current Secretary of MPI, also serves as Viatris's Deputy Global General Counsel and Assistant Secretary, according to Mr. Salus's apparent LinkedIn profile page. (*See* Ex. 46 – W.Va. Secretary of State Business Entity Details for MPI; Ex. 49 – Salus LinkedIn Profile Page).

ANSWER: Paragraph 131 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, venue over MPI is not contested in this Court for purposes of this litigation only. The Domestic Defendants deny the remaining allegations of Paragraph 131.

132. Venue is proper in this district for Mylan Teoranta pursuant to the provisions of 28 U.S.C. §§ 1391(b), (c), (d) and 1400(b) because Mylan Teoranta is a company organized and existing under the laws of Ireland and may be sued in any judicial district.

ANSWER: Paragraph 132 relates to Mylan Teoranta. Mylan Teoranta has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants deny all allegations set forth in Paragraph 132.

133. Venue is proper in this district for Natco pursuant to the provisions of 28 U.S.C. §§ 1391(b), (c), (d) and 1400(b) because Natco is a company organized and existing under the laws of India and may be sued in any judicial district.

ANSWER: Paragraph 133 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 133 relates to Natco. Natco has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to

state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 133 and therefore deny those allegations.

134. Venue is proper in this district for Gland pursuant to the provisions of 28 U.S.C. §§ 1391(b), (c), (d) and 1400(b) because Gland is a company organized and existing under the laws of India and may be sued in any judicial district.

ANSWER: Paragraph 134 contains legal conclusions and allegations to which no answer is required. To the extent that a response is required, Paragraph 134 relates to Gland. Gland has moved to be dismissed from this lawsuit based on lack of personal jurisdiction and for failure to state a claim. The Domestic Defendants lack sufficient knowledge or information as to the allegations of Paragraph 133 and therefore deny those allegations.

COUNT I
(Infringement Of U.S. Patent No. 8,859,489 By Defendants Under, Inter Alia, 35 U.S.C. § 271(b) and/or (g))

135. Paragraphs 1 through 134 are incorporated by reference as if fully stated herein.

ANSWER: The Domestic Defendants incorporates by reference their responses to Paragraphs 1 through 134 as if fully set forth herein.

136. The ’489 patent is valid and enforceable.

ANSWER: Denied.

137. Upon information and belief, Mylan Teoranta, Natco Pharma Ltd., and Gland Pharma, Ltd. currently infringe and have infringed one or more claims of the ’489 patent, including at least claim 1, either literally or under the doctrine of equivalents, by, *inter alia*, manufacturing generic glatiramer acetate for commercial sale using the methods claimed in the ’489 patent and, without authority, importing that generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products) into the United States or making, offering to sell, selling, or using it within the United States, or inducing others to do the same.

ANSWER: Paragraph 137 relates to Mylan Teoranta, Natco, and Gland. Mylan Teoranta, Natco, and Gland have moved to be dismissed from this lawsuit based on lack of personal

jurisdiction and for failure to state a claim. The Domestic Defendants deny the allegations set forth in Paragraph 137.

138. Upon information and belief, Mylan Pharmaceuticals, Inc., Mylan Inc., and Viatris Inc. have infringed, and are continuing to infringe, and have induced others to infringe, the '489 patent, either literally or under the doctrine of equivalents, by, *inter alia*, importing, without authority, generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products) into the United States or making, offering to sell, selling, or using it within the United States, or inducing others to do the same.

ANSWER: Denied.

139. For example, upon information and belief, Defendants have induced infringement, and continue to induce infringement, of one or more claims of the '489 patent under 35 U.S.C. § 271(b). Defendants actively, knowingly, and intentionally induced, and continue to actively, knowingly, and intentionally induce, infringement of the '489 patent by importing, selling or otherwise supplying generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products); with the knowledge and intent that other Defendants or third parties will use, sell, and/or offer for sale in the United States, and/or import into the United States, the generic glatiramer acetate to infringe the '489 patent; and with the knowledge and intent to encourage and facilitate the infringement through the importation or dissemination of the generic glatiramer acetate and/or the creation and dissemination of promotional and marketing materials, supporting materials, instructions, product manuals, and/or technical information related to the generic glatiramer acetate.

ANSWER: Denied.

140. Defendants have not obtained a license to use the processes claimed in the '489 patent or to import, make, offer for sale, sell, or use in the United States products made by those processes.

ANSWER: Admitted.

141. Upon information and belief, Defendants have acted in concert by assisting with, participating in, encouraging, contributing, aiding and abetting and/or directing the manufacture, marketing, sale, offer to sell and/or import of the Mylan Glatiramer Acetate Products.

ANSWER: Denied.

142. The accused products are glatiramer acetate and products containing the same, manufactured using a process claimed by the '489 patent, literally and/or under the doctrine of equivalents. Upon information and belief, glatiramer acetate is being manufactured using a process claimed by the '489 Patent outside of the United States by Natco, Mylan Teoranta, and/or Gland, working in conjunction with Mylan, which is then imported into

the United States by Defendants, and then sold by Defendants, specifically including at least MPI, Viatris, and Mylan Inc. On October 3, 2017, after MPI had obtained approval to market the Mylan Glatiramer Acetate Products in the United States, Mylan N.V. (now Viatris) stated that it would begin shipping its glatiramer acetate products "imminently," and on October 4, 2017, Mylan N.V. (now Viatris) confirmed that it had launched Glatiramer Acetate Injection 40 mg/mL and 20 mg/mL in the United States. (Ex. 20 – 091646 Approval Letter; Ex. 21 – 206936 Approval Letter; Ex. 25 – 2017.10.03 Mylan Press Release; Ex. 26 – 2017.10.04 Mylan Press Release).

ANSWER: Admitted that MPI launched MPI's GA Products on October 3, 2017. Momenta makes no specific allegations as to the exhibits cited in Paragraph 142 and therefore no response is required as to those exhibits. The Domestic Defendants deny the remaining allegations set forth in Paragraph 142.

143. Upon information and belief, Defendants make, offer to sell, sell and/or import glatiramer acetate that is manufactured using a process claimed by the asserted claims of the '489 patent literally and/or under the doctrine of equivalents.

ANSWER: Denied.

144. Claim 1 of the '489 patent recites as follows:

> *A method for preparing a composition comprising purified glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm and a Mp of 5000–9000 Da, comprising: polymerizing N-carboxy anhydrides of L-alanine, benzyl-protected L-glutamic acid, trifluoroacetic acid (TFA) protected L-lysine and L-tyrosine to generate a protected copolymer (Intermediate-1); treating the protected copolymer with HBr and acetic acid to partially depolymerize the protected copolymer and deprotect benzyl protected groups thereby generating a partially depolymerized product; treating the partially depolymerized product with piperidine to deprotect TFA-protected lysines thereby generating glatiramer acetate; and purifying the glatiramer acetate to create purified glatiramer acetate having a pyro-Glu concentration of 2000-7000 ppm and a Mp of 5000–9000 Da, wherein water is present during the entirety of the depolymerization step in an amount that yields glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm and a Mp of 5000–9000 Da.*

ANSWER: Admitted.

145. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "[a] method for preparing a composition comprising purified glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm." According to Mylan, its ANDA included "rigorous side-by-side analyses, including characterization data, [demonstrating] that Mylan's Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL have the same active ingredient" as Copaxone® (glatiramer acetate injection). (Ex. 25 – 2017.10.03 Press Release). And given the FDA's approval of Mylan's Glatiramer Acetate Products, the FDA also considers those products to have established "sameness" to Copaxone® (glatiramer acetate injection). As the FDA has recognized, pyro-Glu[2] is a process signature for glatiramer acetate synthesis because endo glutamic acid cyclizes to form pyro-Glu under strong acid conditions resulting in cleavage such that pyro-Glu becomes the "new" N terminus. (See Ex. 16 – FDA CP Response, at 18 n.61, 28). The claimed pyro-Glu range is representative of the distribution of pyro-Glu across multiple lots of Copaxone® (glatiramer acetate injection). (*See, e.g.*, Ex. 1 – '489 patent at 4:14–20). Because Mylan has represented, and the FDA has found, that the Mylan Glatiramer Acetate Products are the "same" as Copaxone® (glatiramer acetate injection), upon information and belief, those products share the same pyro-Glu concentration as Copaxone® (glatiramer acetate injection), *i.e.*, the claimed range. Upon information and belief, the Mylan Glatiramer Acetate Products are made from purified glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm.

ANSWER: Admitted that the cited documents contain the quoted language. The Domestic Defendants deny the remaining allegations of Paragraph 145.

146. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products also results in glatiramer acetate having "a Mp of 5000–9000 Da." "Mp", or "peak molecular weight" (*see* Ex. 1 – '489 Patent, at 4:42–45), is the molecular weight corresponding to the peak of the distribution curve of molecular weights in a composition. Like pyro-Glu concentration, "[m]olecular [w]eight [d]istribution" is one of the physicochemical properties of glatiramer acetate which must match that of Copaxone® (glatiramer acetate injection). (*See* Ex. 16 – FDA CP Response, at 23). And the glatiramer acetate in Copaxone® (glatiramer acetate injection) has a peak average molecular weight of 5000–9000 Da. (*See id*. at 24; Ex. 15 – Copaxone Package Insert, at 3). Accordingly, the approved label for Mylan's 20 mg/mL and 40 mg/mL Glatiramer Acetate Products states that the average molecular weight of the glatiramer acetate is "5,000 to 9,000 daltons." (*See* Ex. 38 – Mylan 40mg Label, at 6; Ex. 39 – Mylan 20mg Label, at 6).

[2] The FDA CP response refers to pyro-glutamate in particular. Nevertheless, as discussed above, *supra*, p. 5 n.3, a person of skill in the art would understand that pyro-Glu and pyro-glutamate are interchangeable in the context of the '374 and '489 Patents.

ANSWER: Admitted that the FDA-approved prescribing information for MPI's GA Products state that the average molecular weight of glatiramer acetate used in MPI's GA Products is 5,000 – 9,000 daltons. The Domestic Defendants deny the remaining allegations of Paragraph 146.

147. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "polymerizing N-carboxy anhydrides of L-alanine, benzyl-protected L-glutamic acid, trifluoroacetic acid (TFA) protected L-lysine and L-tyrosine to generate a protected copolymer (Intermediate-1)." Defendants manufacture glatiramer acetate using this step of the claimed method because this step of the claimed method follows the fundamental synthetic scheme for glatiramer acetate identified by the FDA. (*See* Ex. 16 – FDA CP Response, at 13 & nn.44–46). Equivalence of the fundamental synthetic scheme is a requirement for FDA approval of generic versions of Copaxone® (glatiramer acetate injection). (Ex. 19 – FDA Draft Guidance, at 1–2). Mylan has represented that it meets the criteria set forth in the FDA CP Response. (*See* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In the first step of Defendants' synthetic process for glatiramer acetate, "N-carboxyanhydrides of the amino acids alanine, glutamic acid, lysine, and tyrosine are combined with the initiator diethylamine to form long chains." (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al.*, No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 79). Defendants use benzyl-protected glutamic acid and TFA-protected lysine as starting materials for Step 1. *Id*. Defendants' Step 1 results in a copolymer retaining benzyl protecting groups on the glutamic acid residues and TFA protecting groups on the lysine residues, i.e., a protected copolymer (Intermediate-1). (*Id*. at 79–80).

ANSWER: Admitted that MPI's GA Products are manufactured using fundamental processes disclosed in the prior art in the 1970s for the manufacturing of a product that became known as Copaxone®. *See* U.S. Patent No. 3,849,550; U.S. Patent No. 5,800,808. The Domestic Defendants deny the remaining allegations set forth in Paragraph 147.

148. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "treating the protected copolymer with HBr and acetic acid to partially depolymerize the protected copolymer and deprotect benzyl protected groups thereby generating a partially depolymerized product." This step is also part of the fundamental glatiramer acetate synthetic scheme, (*see* Ex. 16 – FDA CP Response, at 13–14 & nn.44–46; Ex. 19 – FDA Draft Guidance, at 2), which Mylan has represented that it follows, (see Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In the second step of Defendants' synthetic process for glatiramer acetate, the protected copolymer is treated with HBr/acetic acid, removing the benzyl protecting groups and cleaving the polypeptide chains. (Ex. 58 – Order, *Teva*

Pharms. USA, Inc. et al. v. Sandoz, Inc., et al., No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 80 ("[T]he addition of HBR/acetic acid serves two purposes. First, it removes the benzyl protecting groups from the glutamic acids. Second, it cleaves, or cuts, the polypeptide chains.")). The result of this step is a partially depolymerized copolymer retaining TFA protecting groups. *Id*.

ANSWER: Admitted that MPI's GA Products are manufactured using fundamental processes disclosed in the prior art in the 1970s for the manufacturing of a product that became known as Copaxone®. *See* U.S. Patent No. 3,849,550; U.S. Patent No. 5,800,808. The Domestic Defendants deny the remaining allegations set forth in Paragraph 148.

149. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "treating the partially depolymerized product with piperidine to deprotect TFA-protected lysines thereby generating glatiramer acetate." This step is also part of the fundamental glatiramer acetate synthetic scheme required by the FDA, (*see* Ex. 16 – FDA CP Response, at 13–14 & nn.44–46; Ex. 19 – FDA Draft Guidance, at 2), which Mylan has represented that it follows (*see* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In the third step of Defendants' synthetic process for glatiramer acetate, the partially depolymerized copolymer is treated with piperidine to remove the TFA protecting groups from lysine residues. (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz. Inc., et al.*, No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 83–84 ("In Step 3 of Mylan's process, TFA-copolymer-1 is treated with piperidine, which removes the TFA protecting groups from the lysines.")). The result of this step is crude glatiramer acetate. (*See id*; Ex. 16 – FDA CP Response, at 13–14 and nn.44–46).

ANSWER: Admitted that MPI's GA Products are manufactured using fundamental processes disclosed in the prior art in the 1970s for the manufacturing of a product that became known as Copaxone®. *See* U.S. Patent No. 3,849,550; U.S. Patent No. 5,800,808. The Domestic Defendants deny the remaining allegations set forth in Paragraph 149.

150. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "purifying the glatiramer acetate to create purified glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm and a Mp of 5000–9000 Da." The fourth step of Defendants' synthetic process for glatiramer acetate is purification by diafiltration using acetic acid. (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz. Inc., et al.*, No.1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 84 ("In Step 4 of Mylan's process . . . the resulting product from Step 3 is purified by diafiltration using acetic acid.")). Upon information and belief, purification is a step that Defendants perform

as part of commercial manufacture. As discussed above, Mylan's Glatiramer Acetate Products are prepared from glatiramer acetate considered by the FDA to have established "sameness" to Copaxone® (glatiramer acetate injection), including having pyro-Glu concentration and Mp within the recited ranges.

ANSWER: Admitted that MPI's GA Products are manufactured using fundamental processes disclosed in the prior art in the 1970s for the manufacturing of a product that became known as Copaxone®. *See* U.S. Patent No. 3,849,550; U.S. Patent No. 5,800,808. The Domestic Defendants deny the remaining allegations set forth in Paragraph 150.

151. Upon information and belief, in Defendants' manufacturing process for the Mylan Glatiramer Acetate Products, "water is present during the entirety of the depolymerization step in an amount that yields glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm and a Mp of 5000–9000 Da." The FDA guidance for approval of generic glatiramer acetate notes that water has a role in the cleavage reactions during the partial depolymerization step. (Ex. 16 – FDA CP Response, at 25–26 n.87; Ex. 19 – FDA Draft Guidance, at 1 n.1). The FDA has further advised ANDA applicants like Mylan that "equivalence of [] structural signatures" like those resulting from the cleavage during partial depolymerization is necessary to ensure that a proposed generic glatiramer acetate will be the same as Copaxone® (glatiramer acetate injection). (Ex. 16 – FDA CP Response, at 26). Given the FDA's publication of the role of water in that depolymerization step, and the FDA's simultaneous advisement that the parameters of that depolymerization step must be controlled to ensure sameness with Copaxone® (glatiramer acetate injection), upon information and belief, Defendants control the presence of water during the depolymerization step to control the commercial manufacturing process of generic glatiramer acetate, due to the relationship between water, pyro-Glu concentration, and peak molecular weight. (*See* Ex. 1 – '489 Patent, at 4:21–45 (discussing relationship between water, pyro-Glu concentration, and peak molecular weight)). Specifically, upon information and belief, Defendants ensure that water is present during the entirety of the depolymerization step in an amount that yields glatiramer acetate having a pyro-Glu concentration and Mp within the claimed ranges.

ANSWER: Denied.

152. Alternatively, to the extent the Mylan Glatiramer Acetate Products are not manufactured by a process that literally falls within the claims of the '489 patent, upon information and belief, the Mylan Glatiramer Acetate Products are manufactured by a method that performs substantially the same function in substantially the same way with substantially the same result as the methods claimed in the '489 patent. In addition, Defendants' Mylan Glatiramer Acetate Products are manufactured using a method that is insubstantially different from the methods claimed in the '489 patent. For example, like the methods claimed in the '489 patent, Defendants' manufacturing process for their Mylan Glatiramer Acetate Products

ensures that those products are the same as the active ingredient in Copaxone®. (*See* Ex. 25 – 2017.10.03 Mylan Press Release, at 1–2; Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13).

ANSWER: Denied.

153. Upon information and belief, Mylan has had knowledge and notice of the '489 patent and is knowingly and willfully infringing the '489 patent.

ANSWER: Denied.

154. Mylan's conduct in infringing the '489 patent renders this case exceptional within the meaning of 35 U.S.C. § 285.

ANSWER: Denied.

COUNT II
(Infringement Of U.S. Patent No. 9,395,374 By Defendants Under, *Inter Alia*, 35 U.S.C. § 271(b) and/or (g))

155. Paragraphs 1 through 154 are incorporated by reference as if fully stated herein.

ANSWER: The Domestic Defendants incorporate by reference their responses to Paragraphs 1 through 154 as if fully stated herein.

156. The '374 patent is valid and enforceable.

ANSWER: Denied.

157. Upon information and belief, Mylan Teoranta, Natco Pharma Ltd., and Gland Pharma, Ltd. currently infringe and have infringed one or more claims of the '374 patent, including at least claim 1, either literally or under the doctrine of equivalents, by, *inter alia*, manufacturing generic glatiramer acetate for commercial sale using the methods claimed in the '374 patent and, without authority, importing that generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products) into the United States or making, offering to sell, selling, or using it within the United States, or inducing others to do the same.

ANSWER: Paragraph 157 relates to Mylan Teoranta, Natco, and Gland. Mylan Teoranta, Natco, and Gland have moved to be dismissed form this lawsuit based on lack of personal

jurisdiction and for failure to state a claim. The Domestic Defendants deny the allegations set forth in Paragraph 157.

158. Upon information and belief, Mylan Pharmaceuticals, Inc., Mylan Inc., and Viatris Inc. have infringed, and are continuing to infringe, and have induced others to infringe, the '374 patent, either literally or under the doctrine of equivalents, by, *inter alia*, importing, without authority, generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products) into the United States or making, offering to sell, selling, or using it within the United States, or inducing others to do the same.

ANSWER: Denied.

159. For example, upon information and belief, Defendants have induced infringement, and continue to induce infringement, of one or more claims of the '374 patent under 35 U.S.C. § 271(b). Defendants actively, knowingly, and intentionally induced, and continue to actively, knowingly, and intentionally induce, infringement of the '374 patent by importing, selling, or otherwise supplying generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products); with the knowledge and intent that other Defendants or third parties will use, sell, and/or offer for sale in the United States, and/or import into the United States, the generic glatiramer acetate to infringe the '374 patent; and with the knowledge and intent to encourage and facilitate the infringement through the importation or dissemination of the generic glatiramer acetate and/or the creation and dissemination of promotional and marketing materials, supporting materials, instructions, product manuals, and/or technical information related to the generic glatiramer acetate.

ANSWER: Denied.

160. Defendants have not obtained a license to use the processes claimed in the '374 patent or to import, use, make, offer for sale, or sell in the United States products made by those processes.

ANSWER: Admitted.

161. Upon information and belief, Defendants have acted in concert by assisting with, participating in, encouraging, contributing, aiding and abetting and/or directing the manufacture, marketing, sale, offer to sell and/or import of the Mylan Glatiramer Acetate Products.

ANSWER: Denied.

162. The accused products are glatiramer acetate and products containing the same, manufactured using a process claimed by the '374 patent, literally and/or under the doctrine of equivalents. Upon information and belief, glatiramer acetate is being manufactured using a process claimed by the '374 patent outside of the United States by Natco, Mylan Teoranta, and/or Gland, working in conjunction with Mylan, which is then imported into the United States by Defendants, and then sold by Defendants, specifically including at least MPI, Viatris, and Mylan Inc. On October 3, 2017, after MPI had obtained approval to market the Mylan Glatiramer Acetate Products in the United States, Mylan N.V. (now Viatris) stated that it would begin shipping its glatiramer acetate products "imminently," and on October 4, 2017, Mylan N.V. (now Viatris) confirmed that it had launched Glatiramer Acetate Injection 40 mg/mL and 20 mg/mL in the United States. (Ex. 20 – 091646 Approval Letter; Ex. 21 – 206936 Approval Letter; Ex. 25 – 2017.10.03 Mylan Press Release; Ex. 26 – 2017.10.04 Mylan Press Release).

ANSWER: Admitted that MPI launched MPI's GA Products on October 3, 2017. The Domestic Defendants deny the allegations set forth in Paragraph 162.

163. Upon information and belief, Defendants make, offer to sell, sell and/or import glatiramer acetate using a process claimed by the asserted claims of the '374 patent literally and/or under the doctrine of equivalents.

ANSWER: Denied.

164. Claim 1 of the '374 patent recites as follows:

> *A method for manufacturing a pharmaceutical composition comprising glatiramer acetate, the method comprising:*
>
> *preparing an amino acid copolymer of L-glutamic acid, L-alanine, L-lysine, and L-tyrosine, wherein the preparing step comprises co-polymerizing N-carboxy anhydrides of L-alanine, benzyl-protected L-glutamic acid, trifluoroacetic acid (TFA)-protected L-lysine, and L-tyrosine to generate a first material; treating the first material to deprotect the benzyl-protected L-glutamic acid therein and to partially depolymerize the first material, thereby generating a second material; treating the second material to deprotect the TFA-protected L-lysine to produce a third material; and purifying the third material, to thereby produce the copolymer of L-glutamic acid, L-alanine, L-lysine, and L-tyrosine;*
>
> *measuring pyro-glutamate content of the copolymer in a sample of the copolymer;*
>
> *measuring the peak average molecular weight (Mp) of the copolymer;*

processing the copolymer to produce a pharmaceutical composition comprising glatiramer acetate only if the measured pyro-glutamate content of the copolymer in the sample is within 2000–7000 parts per million (ppm) on a dry weight/dry weight basis,

thereby producing a pharmaceutical composition comprising glatiramer acetate.

ANSWER: Admitted.

165. Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "[a] method for manufacturing a pharmaceutical composition comprising glatiramer acetate." As discussed above, the active pharmaceutical ingredient of the Mylan Glatiramer Acetate Products is glatiramer acetate.

ANSWER: Admitted that the active pharmaceutical ingredient of MPI's GA Products is glatiramer acetate. The Domestic Defendants deny any remaining allegations of Paragraph 165.

166. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "preparing an amino acid copolymer of L-glutamic acid, L-alanine, L-lysine, and L-tyrosine, wherein the preparing step comprises co-polymerizing N-carboxy anhydrides of L-alanine, benzyl-protected L-glutamic acid, trifluoroacetic acid (TFA)-protected L-lysine, and L-tyrosine to generate a first material." Defendants manufacture glatiramer acetate by this step of the claimed method because this step of the method follows the fundamental synthetic scheme for glatiramer acetate identified by the FDA. (*See* Ex. 16 – FDA CP Response, at 13 and nn.44–46). Equivalence of fundamental synthetic scheme is a requirement for FDA approval of generic versions of Copaxone® (glatiramer acetate injection). (Ex. 19 – FDA Draft Guidance, at 1–2). Mylan has represented that it meets the criteria set forth in the FDA CP Response. (*See* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In the first step of Defendants' synthetic process for glatiramer acetate, "N-carboxyanhydrides of the amino acids alanine, glutamic acid, lysine, and tyrosine are combined with the initiator diethylamine to form long chains." (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al.*, No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 79). Defendants use benzyl-protected glutamic acid and TFA-protected lysine as starting materials for Step 1. *Id*. Defendants' Step 1 results in a copolymer retaining benzyl protecting groups on the glutamic acid residues and TFA protecting groups on the lysine residues, *i.e.*, a protected copolymer ("a first material"). (*See id*.).

ANSWER: Admitted that MPI's GA Products are manufactured using fundamental processes disclosed in the prior art in the 1970s for the manufacturing of a product that became known as

Copaxone®. *See* U.S. Patent No. 3,849,550; U.S. Patent No. 5,800,808. The Domestic Defendants deny the remaining allegations set forth in Paragraph 166.

167. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "treating the first material to deprotect the benzyl-protected L-glutamic acid therein and to partially depolymerize the first material, thereby generating a second material." This step is also part of the fundamental glatiramer acetate synthetic scheme, (*see* Ex. 16 – FDA CP Response, at 13–14 and nn.44–46; Ex. 19 – FDA Draft Guidance, at 2), which Mylan has represented that it follows, (see Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In the second step of Defendants' synthetic process for glatiramer acetate, the protected copolymer is treated with HBr/acetic acid, removing the benzyl protecting groups and cleaving the polypeptide chains. (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al.*, No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 80 ("[T]he addition of HBR/acetic acid serves two purposes. First, it removes the benzyl protecting groups from the glutamic acids. Second, it cleaves, or cuts, the polypeptide chains.")). The result of this step is a partially depolymerized copolymer retaining TFA protecting groups (*i.e.*, a "second material"). *Id*.

ANSWER: Admitted that MPI's GA Products are manufactured using fundamental processes disclosed in the prior art in the 1970s for the manufacturing of a product that became known as Copaxone®. *See* U.S. Patent No. 3,849,550; U.S. Patent No. 5,800,808. The Domestic Defendants deny the remaining allegations set forth in Paragraph 167.

168. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "treating the second material to deprotect the TFA-protected L-lysine to produce a third material." This step is also part of the fundamental glatiramer acetate synthetic scheme required by the FDA, (*see* Ex. 16 – FDA CP Response, at 13–14 & nn.44– 46; Ex. 19 – FDA Draft Guidance, at 2), which Mylan has represented that it follows, (*see* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In the third step of Defendants' synthetic process for glatiramer acetate, the partially depolymerized copolymer is treated with piperidine to remove the TFA protecting groups from lysine residues. (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al.*, No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 83–84 ("In Step 3 of Mylan's process, TFA-copolymer-1 is treated with piperidine, which removes the TFA protecting groups from the lysines.")). The result of this step is crude glatiramer acetate (*i.e.*, a "third material"). (*See id*; Ex. 16 – FDA CP Response, at 13–14 and nn.44–46).

ANSWER: Admitted that MPI's GA Products are manufactured using fundamental processes disclosed in the prior art in the 1970s for the manufacturing of a product that became known as Copaxone®. *See* U.S. Patent No. 3,849,550; U.S. Patent No. 5,800,808. The Domestic Defendants deny the remaining allegations set forth in Paragraph 168.

169. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "purifying the third material, to thereby produce the copolymer of L-glutamic acid, L-alanine, L-lysine, and L-tyrosine." The fourth step of Defendants' synthetic process for glatiramer acetate is purification by diafiltration using acetic acid. (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al.*, No.1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 84 ("In Step 4 of Mylan's process . . . the resulting product from Step 3 is purified by diafiltration using acetic acid.")). Upon information and belief, purification is a step that Defendants perform as part of commercial manufacture. As discussed above, the resulting Mylan Glatiramer Acetate Products are copolymers of L-glutamic acid, L-alanine, L-lysine, and L-tyrosine. (*See, e.g.*, Ex. 38 – Mylan 40mg Label, at 6; Ex. 39 – Mylan 20mg Label, at 6).

ANSWER: Admitted that MPI's GA Products are manufactured using fundamental processes disclosed in the prior art in the 1970s for the manufacturing of a product that became known as Copaxone®. *See* U.S. Patent No. 3,849,550; U.S. Patent No. 5,800,808. The Domestic Defendants deny the remaining allegations set forth in Paragraph 169.

170. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "measuring pyro-glutamate content of the copolymer in a sample of the copolymer." Pyro-glutamate is a process signature for glatiramer acetate synthesis because endo glutamic acid cyclizes to form pyro-glutamate under strong acid conditions resulting in cleavage such that pyro-glutamate becomes the "new" N terminus. (*See* Ex. 16 – FDA CP Response, at 18 n.61, 28). The FDA confirms assessing termini is key to process control and evaluation during glatiramer acetate synthesis. (*See* Ex. 16 – FDA CP Response, at 28; Ex. 19 – FDA Draft Guidance, at 3). Specifically, comparison of "[s]tructural signatures for polymerization and depolymerization" of potential glatiramer acetate batches to Copaxone® (glatiramer acetate injection) batches, such as "the relative proportion of amino acids present at position 1 of the N-termini of glatiramer acetate," is one of the four criteria the FDA uses to establish active ingredient "sameness." (*See* Ex. 16 – FDA CP Response, at 21, 28). Mylan has represented that it meets the criteria set forth in the FDA CP Response. (See Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). Mylan indeed represented that its ANDA included "rigorous side-by-side analyses, including characterization data, [demonstrating] that Mylan's Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL have

the same active ingredient" as Copaxone® (glatiramer acetate injection). (Ex. 25 – 2017.10.03 Mylan Press Release, at 1–2). In addition, measuring pyro-glutamate is essential to control batch-to-batch variability because pyro-glutamate is a critical process signature that allows a manufacturer to tell if the manufacturing process is working properly. (*See, e.g.*, Ex. 2 – '374 patent, at 9:26–10:11). Upon information and belief, Defendants thus at least measure the pyro-glutamate content of the glatiramer acetate in the Mylan Glatiramer Acetate Products as a quality control measure.

ANSWER: Admitted that MPI's GA Products are manufactured using fundamental processes disclosed in the prior art in the 1970s for the manufacturing of a product that became known as Copaxone®. *See* U.S. Patent No. 3,849,550; U.S. Patent No. 5,800,808. The Domestic Defendants deny the remaining allegations set forth in Paragraph 170.

171. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "measuring the peak average molecular weight (Mp) of the copolymer." The average molecular weight of the polypeptide chains is specified in the approved label for Mylan's 20 mg/mL and 40 mg/mL glatiramer acetate products. (*See* Ex. 38 – Mylan 40mg Label, at 6; Ex. 39 – Mylan 20mg Label, at 6). The fundamental reaction scheme for glatiramer acetate specified in the FDA CP response also contemplates controlling the manufacturing process in order to obtain glatiramer acetate of a molecular weight within 5,000 to 9,000 Da. (*See* Ex. 16 – FDA CP Response, at 13 n.44). Mylan has represented that it follows this process. (*See* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In addition, to be approved as a generic, Mylan would have had to show that its glatiramer acetate's molecular weight distribution matches that of Copaxone® (glatiramer acetate injection). (*See* Ex. 16 – FDA CP Response, at 23–24). Thus, since Mylan's Glatiramer Acetate Products have been approved as generic versions of Copaxone® (glatiramer acetate injection), upon information and belief, Defendants measure peak average molecular weight as part of the commercial manufacturing process.

ANSWER: Admitted that MPI's GA Products are manufactured using fundamental processes disclosed in the prior art in the 1970s for the manufacturing of a product that became known as Copaxone®. *See* U.S. Patent No. 3,849,550; U.S. Patent No. 5,800,808. The Domestic Defendants deny the remaining allegations set forth in Paragraph 171.

172. Upon information and belief, the information generated by Defendants' measurements of the peak average molecular weight and pyro-glutamate content of their Mylan Glatiramer Acetate Products is routinely (*i.e.*, habitually, regularly, and repeatedly) recorded and retained. Upon information and belief, Defendants perform these quality control

measurements as a part of their commercial production process for each batch of the Mylan Glatiramer Acetate Products that they manufacture.

ANSWER: Admitted that MPI's GA Products are manufactured using fundamental processes disclosed in the prior art in the 1970s for the manufacturing of a product that became known as Copaxone®. *See* U.S. Patent No. 3,849,550; U.S. Patent No. 5,800,808. The Domestic Defendants deny the remaining allegations set forth in Paragraph 172.

173. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "processing the copolymer to produce a pharmaceutical composition comprising glatiramer acetate only if the measured pyro-glutamate content of the copolymer in the sample is within 2000–7000 parts per million (ppm) on a dry weight/dry weight basis." The claimed pyro-glutamate range is representative of the distribution of pyro-glutamate across multiple lots of Copaxone® (glatiramer acetate injection). (*See* Ex. 2 – '374 Patent, at Example 5). According to Mylan, its ANDA included "rigorous side-by-side analyses, including characterization data, [demonstrating] that Mylan's Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL have the same active ingredient" as Copaxone® (glatiramer acetate injection). (Ex. 25 – 2017.10.03 Mylan Press Release, at 1–2). In approving Mylan's Glatiramer Acetate Products, the FDA has authorized Mylan to commercialize only such products that are the same as Copaxone® (glatiramer acetate injection). Accordingly, upon information and belief, Defendants' manufacturing process ensures that the Mylan Glatiramer Acetate Products are prepared only from glatiramer acetate batches having pyro-glutamate within a range matching Copaxone® (glatiramer acetate injection), *i.e.*, within the claimed range. Upon information and belief, the Mylan Glatiramer Acetate Products are made only from glatiramer acetate having pyro-glutamate content within 2000–7000 parts per million (ppm) on a dry weight/dry weight basis.

ANSWER: Denied.

174. Thus, upon information and belief, Defendants control and monitor the pyro-glutamate levels and peak average molecular weight as steps in the manufacturing process for Mylan's Glatiramer Acetate Products as claimed in the '374 patent, and "thereby produc[e] a pharmaceutical composition comprising glatiramer acetate."

ANSWER: Denied.

175. Alternatively, to the extent the Mylan Glatiramer Acetate Products are not manufactured by a process that literally falls within the claims of the '374 patent, upon information and belief, the Mylan Glatiramer Acetate Products are manufactured by a method that performs substantially the same function in substantially the same way with substantially the same

result as the methods claimed in the '374 patent. In addition, Defendants' Mylan Glatiramer Acetate Products are manufactured using a method that is insubstantially different from the methods claimed in the '374 patent. For example, like the methods claimed in the '374 patent, Defendants' manufacturing process for their Mylan Glatiramer Acetate Products ensures that those products are the same as the active ingredient in Copaxone®. (*See* Ex. 25 – 2017.10.03 Mylan Press Release, at 1–2; Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13).

ANSWER: Denied.

176. Upon information and belief, Mylan has had knowledge of and notice of the '374 patent and is knowingly and willfully infringing the '374 patent.

ANSWER: Denied.

177. Mylan's conduct in infringing the '374 patent renders this case exceptional within the meaning of 35 U.S.C. § 285.

ANSWER: Denied.

RESPONSE TO MOMENTA'S PRAYER FOR RELIEF

Momenta is not entitled to any relief sought in their Prayer for Relief.

***

Any allegation in the Complaint and documents purported to be incorporated therein not specifically admitted in the paragraphs above is denied.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not expressly admitted, the Domestic Defendants assert the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiff.

FIRST SEPARATE DEFENSE

Momenta fails to state a claim upon which relief can be granted.

SECOND SEPARATE DEFENSE

Momenta fails to state a claim against any Defendant.

THIRD SEPARATE DEFENSE

The claims of the ’489 patent are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

FOURTH SEPARATE DEFENSE

The claims of the ’374 patent are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

FIFTH SEPARATE DEFENSE

The Domestic Defendants have not infringed, are not infringing, and will not infringe, directly or indirectly, any valid or enforceable claims of the ’489 patent, either literally or under the doctrine of equivalents.

SIXTH SEPARATE DEFENSE

The Domestic Defendants have not infringed, are not infringing, and will not infringe, directly or indirectly, any valid or enforceable claims of the ’374 patent, either literally or under the doctrine of equivalents.

SEVENTH SEPARATE DEFENSE

Even if the Domestic Defendants were to infringe claims of the ’489 and the ’374 patents, Momenta would not be entitled to injunctive relief, at least because Momenta cannot show irreparable harm.

EIGHTH SEPARATE DEFENSE

Momenta fails to state a claim under 35 U.S.C. § 271(b) or (g) and is not entitled to relief under those sections of Title 35.

NINTH SEPARATE DEFENSE

Momenta fails to state a claim for an exceptional case.

TENTH SEPARATE DEFENSE

Momenta is estopped from enforcing the patents-in-suit against the Domestic Defendants.

ELEVENTH SEPARATE DEFENSE

The Court lacks personal jurisdiction over defendants Mylan Teoranta, Natco and Gland.

TWELFTH SEPARATE DEFENSE

The Domestic Defendants reserve all defenses, in law or equity, that may now exist or in the future be available on discovery and further factual investigation in this case, including, without limitation, all defenses governed by Rules 8, 9, and 12 of the Federal Rules of Civil Procedure. The Domestic Defendants further reserve the right to supplement and/or amend these defenses.

COUNTERCLAIMS

Counterclaim Plaintiff Mylan Pharmaceuticals Inc. ("MPI") asserts the following counterclaims against Counterclaim Defendant Momenta Pharmaceuticals Inc. ("Momenta").

THE PARTIES

1. MPI is a corporation organized and existing under the laws of West Virginia, having principal place of business at 3711 Collins Ferry Road, Morgantown, WV 26505.

2. On information and belief and according to Momenta's allegations in the Complaint, Momenta is a Delaware corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ 08560.

3. On information and belief and according to Momenta's allegations in the Complaint, Momenta is a wholly owned subsidiary of Johnson & Johnson.

NATURE OF THE ACTION

4. MPI seeks declaratory judgment that (a) the United States Patent No. 8,859,489 ("the '489 patent") and United States Patent No. 9,395,374 ("the '374 patent) (collectively, the "patents-in-suit") are invalid and/or unenforceable, (b) the patents-in-suit are not infringed by MPI's Glatiramer Acetate Injection 20 mg/mL ("MPI's 20 mg GA Products") and Glatiramer Acetate Injection 40 mg/mL ("MPI's 40 mg GA Products") (MPI's 20 mg GA Products and MPI's 20 mg GA Products collectively "MPI's GA Products"), and are not infringed by the making, use, sell, offer for sale, or importation into the United States of MPI's GA Products, and (c) Momenta is not entitled to injunctive relief even if the MPI's GA Products were valid and infringed.

JURISDICTION AND VENUE

5. This counterclaim arises under the Patent Laws of the United States. 35 U.S.C. § 101 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. Further, the Court has jurisdiction over the subject matter of this counterclaim under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 because there is an immediate and real controversy regarding the validity of the Patents-in-Suit.

7. The Court has personal jurisdiction over Momenta for purposes of these counterclaims at least because Momenta maintains this action in this judicial district.

8. Venue is proper in this judicial district for purposes of these counterclaims because Momenta continues to maintain this action in this judicial district.

9. Further, venue is proper in this judicial district for purposes of these counterclaims under 28 U.S.C. §§ 1391 and 1400(b) at least because Momenta maintains this action in this judicial district.

COUNT I

Declaratory Judgment of Invalidity of United States Patent No. 8,859,489

10. MPI incorporates by reference the allegations in the previous paragraphs of its counterclaims.

11. There is an actual, substantial, continuing, and justiciable controversy between Momenta and MPI regarding whether the claims of the '489 patent are invalid.

12. MPI is entitled to a declaration that the claims of the '489 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitations sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

COUNT II

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,859,489

13. MPI incorporates by reference the allegations in the previous paragraphs of its counterclaims.

14. On information and belief, Momenta is the owner of all legal rights, title, and interests in the '489 patent, including the right to enforce the '489 patent. Momenta has asserted its alleged rights against MPI by filing an infringement action.

15. MPI's GA Products have not infringed, will not infringe, and are not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '489 patent.

16. Unless Momenta is enjoined, MPI believes that Momenta will continue to assert that MPI's GA Products are infringing the claims of the '489 patent and will continue to interfere with MPI's business with respect to MPI's Glatiramer Acetate Products.

17. MPI will be irreparably harmed if Momenta is not enjoined from continuing to assert the '489 patent and from interfering with MPI's business.

18. A definite and concrete, real and substantial, justiciable controversy exists between MPI and Momenta concerning MPI's noninfringement of the '489 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

19. MPI is entitled to a declaratory judgment that MPI's GA Products do not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '489 patent.

COUNT III

Declaratory Judgment of No Injunctive Relief for U.S. Patent No. 8,859,489

20. MPI incorporates by reference the allegations in the previous paragraphs of its counterclaims.

21. Momenta will not in fact experience any harm from any MPI sales of MPI's GA Products that have a nexus to the '489 patent claims.

22. Momenta cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages, even if infringement of a valid and enforceable patent were presumed.

23. Momenta is not entitled to any injunctive remedy of any kind.

COUNT IV

Declaratory Judgment of Invalidity U.S. Patent No. 9,395,374

24. MPI incorporates by reference the allegations in the previous paragraphs of its counterclaims.

25. There is an actual, substantial, continuing, and justiciable controversy between Momenta and MPI regarding whether the claims of the ’374 patent are invalid.

26. MPI is entitled to a declaration that claims of the ’374 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

COUNT V

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,395,374

27. MPI incorporates by reference the allegations in the previous paragraphs of its counterclaims.

28. On information and belief, Momenta is the owner of all legal rights, title, and interests in the ’374 patent, including the right to enforce the ’374 patent. Momenta has asserted its alleged rights against MPI by filing an infringement action.

29. MPI’s GA Products have not infringed, will not infringe, and are not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’374 patent.

30. Unless Momenta is enjoined, MPI believes that Momenta will continue to assert that MPI’s GA Products are infringing the claims of the ’374 patent and will continue to interfere with MPI’s business with respect to MPI’s Glatiramer Acetate Products.

31. MPI will be irreparably harmed if Momenta is not enjoined from continuing to assert the ’374 patent and from interfering with MPI’s business.

32. A definite and concrete, real and substantial, justiciable controversy exists between MPI and Momenta concerning MPI's noninfringement of the '374 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

33. MPI is entitled to a declaratory judgment that MPI's GA Products do not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '374 patent.

COUNT VI

Declaratory Judgment of No Injunctive Relief of U.S. Patent No. 9,395,374

34. MPI incorporates by reference the allegations in the previous paragraphs of its counterclaims.

35. Momenta will not in fact experience any harm from any MPI sales of MPI's Glatiramer that have a nexus to the '374 patent.

36. Momenta cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages, even if infringement of a valid and enforceable patent were presumed.

37. Momenta is not entitled to any injunctive remedy of any kind.

PRAYER FOR RELIEF

WHEREFORE, MPI requests that the Court enter Judgment in its favor and against Momenta as follows:

A. Ordering that Momenta's Complaint be dismissed with prejudice and judgment entered in favor of MPI;

B. Denying the relief sought in Momenta's Complaint in its entirety;

C. Declaring each of the claims of U.S. Patent Nos. 8,859,489 and 9,395,374 invalid and/or unenforceable;

D. Declaring that MPI's GA Products do not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of U.S. Patent Nos. 8,859,489 and 9,395,374;

E. Declaring that Momenta is not entitled to any injunctive remedy related to U.S. Patent Nos. 8,859,489 and 9,395,374;

F. Ordering that judgment be entered in favor of MPI on each of its affirmative defenses and any additional defenses discovery may reveal;

G. Enjoining Momenta and its respective officers, employees, agents, representatives, attorneys, and others acting on their behalf from representing to anyone, either directly or indirectly, that MPI's GA Products have infringed, are infringing, or will infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of U.S. Patent Nos. 8,859,489 and 9,395,374;

H. Awarding MPI its costs and expenses in this action;

I. Declaring this case exceptional and awarding MPI its reasonable attorneys' fees and costs pursuant to 35 U.S.C. § 285; and

J. Awarding MPI any further relief this Court may deem just, proper, and equitable.

A JURY TRIAL IS DEMANDED.

Dated: September 19, 2022

Respectfully submitted,

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP

Counsel for Defendants Mylan Pharmaceuticals Inc., Mylan Inc., Viatris Inc., Mylan Teoranta, Natco Pharma Ltd., and Gland Pharma, Ltd.

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CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of September, 2022, I electronically filed the foregoing **DEFENDANTS MYLAN PHARMACEUTICALS INC.'S, MYLAN INC.'S, AND VIATRIS INC.'S ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT WITH DEFENSES AND COUNTERCLAIMS** with the Clerk of the Court using the CM/ECF system which sent notification to all counsel of record, including the following:

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